

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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| DOUG PALUCK and RHONDA PALUCK, as parents and natural guardians on behalf of their minor son, KARL PALUCK, | * | |
| | * | No. 07-889V |
| | * | Judge Charles F. Lettow |
| | * | Special Master Christian J. Moran |
| | * | |
| Petitioners, | * | Filed: May 10, 2013 |
| | * | |
| v. | * | Entitlement; significant aggravation |
| | * | mitochondrial disorder; decision |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | on remand |
| | * | |
| Respondent. | * | |

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Sheila A. Bjorklund, Lommen Abdo Law Firm, Minneapolis, MN, for petitioners;
Chrysovalantis P. Kefalas, United States Dep't of Justice, Washington, DC, for
respondent.

PUBLISHED DECISION ON REMAND DENYING ENTITLEMENT¹

Doug and Rhonda Paluck request compensation on a claim that various vaccines harmed their son, Karl. Their case is proceeding in the National Childhood Vaccine Injury Compensation Program. 42 U.S.C. § 300aa–10 *et seq.* (2006). The statute authorizes recovery when the petitioners establish that

¹ The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa–12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

vaccines either caused a new illness or significantly aggravated a pre-existing condition.

A December 14, 2011 decision (“Entitlement Decision”) found that the Palucks failed to establish that the measles, mumps, and rubella (“MMR”), varicella, and pneumococcal vaccines caused Karl’s illness based upon a failure to establish the factors set forth in Althen v. Secretary of Health & Human Servs., 418 F.3d 1274 (Fed. Cir. 2005). This decision did not determine whether the Palucks’ case should be categorized as either an initial causation claim or a significant aggravation claim. See Decision, 2011 WL 6949326.

The Palucks filed a motion for review. On April 18, 2012, the Court granted this motion, vacated the December 14, 2011 decision, and remanded for additional findings. Opinion and Order, 104 Fed. Cl. 457 (2012). The Court permitted, but did not require, the submission of additional evidence. The Opinion and Order specified that the decision on remand should determine whether “indicia of Karl’s neurodegeneration manifested themselves prior to the vaccinations that occurred January 19, 2005.” Id. at 469. The Opinion and Order also explicitly stated that the Court was “mak[ing] no affirmative findings of its own.” Id. at 484.

The parties were given an opportunity to present additional evidence on remand. However, they did not and the evidentiary record has not changed after the remand.

Karl manifested problems traceable to his central nervous system before he was vaccinated. Thus, the Palucks’ claim is treated as a claim that the vaccinations significantly aggravated his underlying mitochondrial disorder. As discussed extensively below in sections IV.B, IV.C and IV.D, the Palucks have not established that Karl showed the rapid and drastic effects of a vaccination as the theory of their expert, Dr. Frye, predicted. Notably (but not exclusively), Karl’s dramatic decline did not happen until months after the vaccination.

For these reasons, the Palucks have not demonstrated that they meet the standards for entitlement. The Clerk’s Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

I. Procedural History after Remand

After the Opinion and Order remanded the case, the first action was the submission of an order requesting status reports from each side, proposing the next steps in the case. The parties were also instructed to address “the Court’s comments regarding classifying Karl’s case as either a significant-aggravation claim or new-injury claim.” Order, filed Apr. 24, 2012.

The Palucks filed a status report containing four parts. First, the Palucks argued that in the Opinion and Order, the Court “made specific findings as to each Althen prong Upon his careful review of the record in this matter, [the Court] concluded that Petitioners submitted sufficient evidence to meet their burden under all of the three Althen prongs [The special master] needs only to adopt [the Court’s] reasoning and conclusions.” Pet’r Status Rep’t, filed May 7, 2012, at 1. Second, the Palucks argued that Karl’s neurodegeneration after January 19, 2005, constituted a new injury and they were entitled to compensation on that claim. Id. at 3-7. Third, and alternatively, the Palucks argued that even if Karl’s claim were one for significant aggravation, they remain entitled to compensation. Id. at 7. Fourth, the Palucks asserted that “[t]here is no need for additional testimony or submission of evidence as to causation.” Id. at 8.

After filing an unopposed motion for enlargement of time, the Secretary presented her response to petitioners’ status report on June 8, 2012. First, the Secretary summarized portions of the Opinion and Order. Resp’t Resp., filed June 8, 2012, at 1-3. Next, the Secretary contended that Karl’s case is properly classified as a significant aggravation claim and argued that the Palucks have not established that they are entitled to compensation. Id. at 3-8. The Secretary responded to the alternative theory, the new injury claim, in a single sentence. Id. at 8. Finally, the Secretary stated “should the special master decide that the record is insufficient to fully consider petitioners’ claim as one of significant aggravation, respondent does not object to the submission of additional evidence for that purpose.” Id.

An unrecorded status conference was held on June 27, 2012. As set forth in the subsequent order, the parties were informed that their status reports did not answer a question posed by the Court. The Opinion and Order expected resolution of whether “Karl’s neurological, not mitochondrial, symptoms, however defined, were manifested pre-vaccination.” The undersigned commented that the Secretary appeared to have lumped Karl’s neurological problems with Karl’s mitochondrial problems, which was contrary to how the Court framed the issue. The undersigned

also requested that the Palucks explain how Karl's gross motor delay that was found in October 2004, differed from the chiropractor's report of hypertonicity and spasticity in February 2005. Consequently, both sides were ordered to file supplemental briefs. Order, filed July 10, 2012.

The Secretary filed a supplemental brief on August 21, 2012.² Consistent with her previous briefs, the Secretary continued to press the argument that, as a legal matter, Karl's claim should be analyzed as a significant aggravation claim. In the Secretary's view, Karl suffered one continuous process in which his "neurodegeneration . . . developmental delays, and related symptoms are a sequela of Karl's pre-existing mitochondrial disorder." Resp't Br., filed Aug. 21, 2012, at 1. The Secretary asserted that neurological symptoms are not separate from mitochondrial symptoms. Id. at 3. On the topic of mitochondrial disorders, the Secretary stated that she had "no objection to re-opening the record to provide additional evidence on mitochondrial disorders." Id. at 3 n.1.

The Palucks responded. The Palucks argued that "Karl had no neurodegeneration prior to his receipt of vaccine on January 19, 2005." Pet'r Br., filed Aug. 28, 2012, at 2 (capitalization changed without notation). The Palucks reviewed some of the evidence showing Karl's pre-vaccination history. Id. at 2-5. The Palucks interpreted this evidence as consistent with their legal claim that the January 19, 2005 vaccinations caused him a new injury. Id. at 5-7. In conclusion, the Palucks argued against additional evidence. They stated:

It would be a waste of resources in both time and money for this Court to open the record in this matter to receive additional evidence on mitochondrial disorders as suggested in a footnote by Respondent. See Respondent's Suppl Brief, fn 1. There is more than sufficient testimony and medical literature as a matter of record to permit this court to make a determination if this is a cause-in-fact injury case or a significant aggravation injury case.

Id. at 7.

² The Secretary had informally requested additional time to file this brief due to an injury to her attorney. The Palucks did not oppose this request. See order, filed July 30, 2012.

An August 30, 2012 order permitted the Palucks to identify evidence that Karl's gross motor delay was caused by a problem in his muscles, as opposed to his central nervous system ("CNS"). The Palucks responded on September 4, 2012.

An unrecorded status conference was held on September 11, 2012. A primary purpose was to ascertain the Secretary's position regarding the need for additional evidence. In previous filings, the Secretary had stated that she did not object, but the Secretary had not requested additional evidence. In the ensuing status report, the Secretary stated that she "will not at this time move to present additional evidence on the question of whether Karl's pre-vaccination mitochondrial symptoms were central nervous system or musculoskeletal problems." Resp't Status Rep't, filed Sept. 18, 2012, at 2. The next day, the Palucks stated that "[t]his matter is ripe for decision." Pet'r Status Rep't, filed Sept. 19, 2012, at 2.

At the oral argument on the second motion for review, which is discussed below, the parties confirmed that they did not want to present additional evidence:

THE COURT: Was there a consensus between the parties that no further evidentiary proceedings were to be conducted on remand before the Special Master?

[PETITIONER'S COUNSEL]: Yes. Both sides were provided the opportunity to identify whether or not they believe[d] that further hearings were required or further evidence was required to be submitted into the record, and clearly Petitioners determined that there was sufficient evidence in the records to meet our burden of proof.

Oral. Arg. Tr., April 10, 2013, 9:1 to 10:3.³

In combination, the Court's Opinion and Order; the April 24, 2012 order, requesting "next steps;" and the September 11, 2012 order, requesting statements regarding the need for additional evidence presented the parties with several opportunities to obtain additional evidence. The attorneys saw the Court's instructions about the need for the special master to consider, among other topics,

³ Later, on this point, the Court commented that he "has been a little surprised that there weren't further evidentiary proceedings conducted before the Special Master, but I'll leave that aside." Id. at 24:6-8.

the chiropractor's records. The attorneys, presumably, reviewed those records and the testimony from the experts about those records. This process "afford[ed] each party a full and fair opportunity to present its case." Vaccine Rule 3(b)(2). After an opportunity to consider whether additional information would be helpful, each party submitted status reports declaring that additional evidence was not needed. The parties submitted the case for adjudication.⁴

⁴ Conceivably, the undersigned could have exercised his authority to "require the testimony of any person," 42 U.S.C. § 300aa – 12(d)(3)(B)(iii), sua sponte. As a matter of discretion, the undersigned refrained for several reasons. First, the attorneys of record are experienced and competent counsel. They are able to analyze the law and the facts. The attorneys also have access to doctors who can informally advise them as to whether additional evidence may help (or hurt) their cases. Thus, there is little reason for this special master to second-guess the informed decision of the parties not to submit additional evidence, especially because special masters have been cautioned not to interfere with counsel's development of the case. See Boley v. Sec'y of Health & Human Servs., 82 Fed. Cl. 407, 414 (2008), mot. for rev. denied after remand, 86 Fed. Cl. 294 (2009).

Second, as a practical matter, a sua sponte order requiring the testimony of a medical doctor would be difficult to implement. A basic question is who would pay for the doctor's time? In this time of budget austerity, this question matters. This issue alone may account for why special masters have not issued any sua sponte orders compelling unrequested testimony during the undersigned's tenure as a special master.

Third, the compelled testimony of a witness implicates other relationships. For example, the Palucks may have a continuing relationship with Karl's primary pediatrician, Dr. Stephen McDonough, who may wish not to become involved in litigation. Thus, the Federal Circuit has warned that "the specter of a subpoena" could be "a disincentive" for doctors "to treat a vaccine-injured patient." Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1383 (Fed. Cir. 2009).

For these reasons, special masters guide parties in presenting their cases and are willing, when the circumstances justify an order, to compel the production of evidence that a party has requested. See, e.g. Doe 34 v. Sec'y of Health & Human Servs., 87 Fed. Cl. 758, 765 (2009) (ruling that special master did not err in securing participation of a doctor whose testimony the Secretary "had always requested"). After the parties present all their evidence, the special master functions as a finder of fact, albeit one with expertise in the subject. See Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993). One party's disappointment over the outcome of a hearing does not entitle that party another

(. . . continued)

On October 8, 2012, the Palucks filed a second motion for an award of attorneys' fees on an interim basis. After the parties discussed the request, the Palucks filed a stipulation on October 22, 2012. The next day, a decision awarding additional attorneys' fees was entered.

On January 30, 2013, the Palucks filed a motion for review with the Court, arguing that the undersigned's time for issuing a decision expired 90 days after the April 18, 2012 Opinion and Order. After additional briefing and argument, the Court denied the motion for review, finding that the amount of time that case was pending on remand did not constitute "such a passage of time as undue delay tantamount to a failure to exercise jurisdiction on the part of the special master." The Court mandated a decision within 120 days of its May 3, 2013 Opinion and Order.

II. Background of Karl's Medical History

Although the parties draw different conclusions from the facts, there is a basic agreement about them. These facts were detailed in the December 14, 2011 decision and the April 18, 2012 Opinion and Order. The following summary is presented for context. More detailed findings of fact are made throughout sections III. and IV. below.

Karl was born on January 15, 2004. His development appeared to be normal for the first six months or so. During this time, Karl received typical vaccinations at two, four, and six months, without any apparent ill effects from them. See exhibit 5 at 12.

Karl's pediatrician, Dr. McDonough, noticed that Karl was developmentally delayed during an examination when he was eight months old. Exhibit 5 at 111. The doctor referred Karl to a program for children with developmental delays, K.I.D.S. The staff at K.I.D.S. assessed Karl. The ensuing report stated:

Karl's gross motor delays are impacting his ability to achieve age-level skills in other areas of development. Karl has difficulty moving against gravity, which is an important gross motor foundational skill.

opportunity to present further evidence. Sword v. United States, 44 Fed. Cl. 183, 190-91 (1999) (ruling that the special master did not abuse her discretion in denying the respondent's motion to submit additional expert testimony).

. . . When evaluating Karl's muscle tone the passivity in his arms is greater than normal. His arm's consistency is softer than normal and his extensibility provides no resistance to passive movement. . . . Karl has difficulty bringing his hands together to clap or bang cubes together. He does not yet participate in turn-taking games such as pat a cake and peek-a-boo. . . . In order to provide stability in his arms and trunk, Karl fixes his legs. By fixing his legs, Karl presents with slight elevated tone.

Exhibit 15 at 4.⁵

Additionally, the evaluators observed that "Karl is not using many gestures," and "is not approximating sounds made by another person. He tends to produce sounds spontaneously, but does not imitate when a model is provided him." Exhibit 15 at 4-5. The evaluators also noted that "Karl does not respond to specific words or phrases such as 'no, no, Karl.'" Id. at 5. The report recommended that Karl "receive infant development services . . . targeting his speech/language, gross motor, and the delays in fine motor related to low muscle tone." Id.

In this proceeding, the Palucks and the Secretary draw very different conclusions from the K.I.D.S. report. The Palucks interpreted the report as showing that Karl's cognition and language abilities were "absolutely normal," and that any developmental delays "were most prominently gross motor delays, maybe a little bit of fine motor delays." Tr. 101:9-11. The Secretary, on the other hand, saw the report as supporting her view that Karl's cognition and language were below average. To the Secretary, Karl's inability to respond to "no no," for example, was not a "minor trivial thing." Tr. 787:11-13.

⁵ The report's authors define the following three terms: "Passivity refers to the amount of flapping of the child's hand or foot when the evaluator shakes an extremity, thereby imposing multiple quick stretches. Normally the extremity tightens at the wrist or ankle after a few excursions of the hand or foot." Exhibit 15 at 4 n.1. "Consistency refers to the relative firmness of muscle tissue, which is evaluated by palpation. Normally the muscle feels sturdy but there is some yielding to pressure." Id. at 4 n.2. "Extensibility refers to the capacity of a muscle to elongate when a quick stretch is imposed on it. . . . Typically a normal, graded resistance is felt throughout the range of motion." Id. at 4 n.3

Around this same time, Karl was having two other problems. He was having recurrent otitis media and recurrent erythema multiforme.⁶ These problems continued to afflict Karl periodically from approximately October 2004 to April 2005. Karl was seen by his doctors for these two problems as necessary.

On December 27, 2004, Dr. McDonough saw Karl. Dr. McDonough recorded that “[n]eurologic examination reveals normal muscle tone. There is no ankle clonus. Deep tendon reflexes appear to be symmetrical. He has good head control and fairly good truncal control but is not pulling himself to stand or crawling yet.” Exhibit 3 at 5. His assessment of Karl was “[b]ilateral serous otitis media; rash, possible erythema multiforme, . . . and possible mild gross motor delay.” Id. at 5-6.

Karl’s next appointment with Dr. McDonough was on January 19, 2005, which was his one-year well-baby appointment. Karl received doses of the measles, mumps, and rubella vaccine, the pneumococcal vaccine, and the varicella vaccine. Dr. McDonough recorded a history about Karl’s current functioning. At this appointment, Dr. McDonough referred Karl to physical and occupational therapy. Exhibit 3 at 3. Instead of taking Karl to a therapist as their pediatrician recommended, the Palucks brought him to a chiropractor. Exhibit 12.

On March 24, 2005, Dr. McDonough referred Karl, then 14 months of age, to a pediatric neurologist, Dr. Siriwan Kriengkrairut, “for gross motor delay, global developmental delay, and hypertonicity.” Exhibit 3 at 7. In his referral, Dr. McDonough also noted that Karl “has had recurrent erythema multiforme.” Karl saw both Dr. McDonough and Dr. Kriengkrairut in April. See Exhibit 3 at 9-11 (Dr. McDonough), 83-85 (Dr. Kriengkrairut).

Karl had relatively little interaction with health care providers in May and June 2005. On July 12, 2005, Karl had a series of seizures. He was hospitalized for approximately three weeks. Despite investigation, the doctors did not identify the cause of Karl’s seizures.

⁶ Erythema multiforme is “an acute eruption of macules, papules, or subepidermal vesicles presenting a multiform appearance.” Stedman’s Medical Dictionary 667 (28th ed. 2006). While “the eruption is usually self-limited . . . , [it] may be recurrent or may run a severe course.” Id.

After the July 2005 hospitalizations, Karl was tested extensively.

Eventually, samples obtained from Karl were sent to Baylor College of Medicine for mitochondrial diagnostic testing. Exhibit 18 at 60-61. The electron transport chain enzymes test conducted on muscle tissue by Baylor showed increased citrate synthetase activity, “suggesting mitochondrial proliferation, which can be an adaptive response to mitochondrial function.” These results, while “not reflect[ing] any specific diagnostic pattern,” do “fulfill a minor diagnostic criterion for a mitochondrial disorder,” id. at 60, indicating that Karl most likely suffered from a disorder in his mitochondria. The precise nature of Karl’s mitochondrial problem, however, is not known. See Tr. 503:22-25 (Dr. Snodgrass: “I think he has a progressive disease and that it’s probably a primary mitochondrial disease, but it might be a progressive disease that is not a primary mitochondrial disease.”); Tr. 88:24-25 (Dr. Frye: “Using the modified Walker criteria or the Morava criteria, he meets criteria for a probable mitochondrial disorder . . . he is rated as probable by both criteria.”).

Mitochondria are organelles (parts of cells) that supply energy to cells. “Mitochondrial disease is not a single entity but, rather a heterogenous group of disorders characterized by impaired energy production due to genetically based oxidative phosphorylation dysfunction. Together, these disorders constitute the most common neurometabolic disease of childhood.” Opinion and Order, 104 Fed. Cl. at 463 n.8, quoting Entitlement Decision, at *1, quoting exhibit E (Richard H. Haas et al., Mitochondrial Disease: A Practical Approach for Primary Care Physicians, 120 Pediatrics 1326, 1327 (2007)) (internal quotation marks omitted). “Mitochondrial diseases are usually progressive and multisystemic. Typically affected organs are those with a high energy demand, including skeletal and cardiac muscle, . . . and the central nervous system.” Exhibit E (Haas) at 1327.

Although Karl’s treating doctors have not identified the exact error in Karl’s mitochondria, both testifying experts agree that Karl suffers from a mitochondrial disease. Tr. 88:23-89:2 (Dr. Frye), 413:1-20 (Dr. Snodgrass); see also Tr. 27:10-11 (Petitioners’ attorney: “[a]n undisputed fact from both experts is that Karl has a mitochondrial dysfunction”). Additionally, and importantly, the experts also agree that Karl was born with his mitochondrial defect. Tr. 80:24-81:8 (Dr. Frye), 260:5-10, 377:7-11 (Dr. Snodgrass). The fact that Karl was born with the mitochondrial disorder means that the Palucks cannot claim (and do not claim) that any vaccination caused Karl’s mitochondrial disorder.

Instead, the Palucks argue that “Karl’s devastating neurological regression following receipt of five vaccines on January 19, 2005 is a new injury.” The basis

for this argument is that, to the Palucks, Karl “exhibited no signs of central nervous system damage, with resultant neurodegeneration, until after receipt of the January 2005 vaccines.” Pet’r Status Rep’t, filed May 7, 2012, at 2.

The Secretary disagrees. The Secretary argues that the Palucks’ “claim is best analyzed as a significant aggravation claim.” For the Secretary, Karl’s “neurodegeneration, developmental delays, and related symptoms are a sequela of Karl’s pre-existing mitochondrial disorder.” Resp’t Resp., filed June 8, 2012, at 4. This is the first issue requiring resolution.

III. Initial Causation or Significant Aggravation

The Court’s framing of this issue controls the analytical structure on remand. See 42 U.S.C. § 300aa-12(e)(2)(c) (empowering the Court of Federal Claims to remand “to the special master for further action in accordance with the court’s direction”); Hanlon v. Sec’y of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998) (a decision from the Court of Federal Claims is binding on a special master in the same case on remand), aff’d, 191 F.3d 1344 (Fed. Cir. 1999). In its Opinion and Order, the Court stated:

A related second issue^[7] is whether indicia of Karl’s neurodegeneration manifested themselves prior to the vaccinations

⁷ The Court’s initial issue was “the precise definition of Karl’s injury.” The Court, as set forth in the text, queried whether “neurodegeneration” is the appropriate metric. Both before and after remand, the parties have presented evidence and argument based upon a claim of “neurodegeneration.” For examples of pre-remand arguments, see Pet’r Posthr’g Br., filed Feb. 18, 2011, at 28 (sequence of medical events “support [petitioners’] contention that [Karl’s] vaccines cause[d] [his] neurodegeneration”); Resp’t Posthr’g Br., filed Feb. 18, 2011, at 43 (arguing petitioners’ evidence “is irrelevant to a hypothesis that posits a relationship between vaccinations and neurodegeneration”). For examples of post-remand arguments, see Pet’r Status Rep’t., filed May 7, 2012, at 7 (all the evidence “clearly demonstrates that Karl Paluck suffered a new injury – devastating neurodegeneration – following receipt of his . . . vaccines”); Pet’r Br., filed Aug. 28, 2012, at 7 (“[Karl] had neurodegeneration *after* receipt of the . . . vaccines.”); Resp’t Br., filed Aug. 21, 2012 (“There is no reliable evidence . . . that neurodegeneration . . . represent[s] distinct, new injuries from [Karl’s]

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that occurred January 19, 2005. The parties have framed these issues in simplified terms, i.e., whether Karl was progressing or regressing developmentally prior to his vaccinations. With a genetic abnormality of the type inhering in Karl, this may not be the proper focus for determination. Rather, based on the record as it stands, voluminous as it may be, it is medically and scientifically uncertain whether developmental progress or regress is a valid measure to assess the pre-vaccination condition of a very young child with Karl's type of mitochondrial defect, or whether another indicator should be employed. If Karl's neurological, not mitochondrial, symptoms, however defined, were manifested pre-vaccination, then Karl's case involves a significant-aggravation claim. See [Shalala v. Whitecotton, 514 U.S. [268,] 274 [(1995)]. If not, then Karl's case concerns a new-injury claim.

Opinion and Order, 104 Fed. Cl. at 469. The critical portion of this passage is the Court's statement that "If Karl's neurological, not mitochondrial, symptoms, however defined, were manifested pre-vaccination, then Karl's case involves a significant-aggravation claim." This statement directs an examination of Karl's health before vaccination, looking for evidence of "neurological, not mitochondrial, symptoms."⁸

mitochondrial disorder."). Thus, this decision will continue to use the parties' characterization of Karl's injury as one of "neurodegeneration."

⁸ The Court's phrase "neurological, not mitochondrial, symptoms, however defined" seems to distinguish neurological symptoms from mitochondrial symptoms. See orders, filed July 20, 2012 and July 30, 2012 (requesting supplemental briefs on this topic).

The Secretary stated that differentiating between neurological symptoms and mitochondrial symptoms "is contrary to the medical understanding of mitochondrial disorders, as well as contrary to the testimony of both parties' experts." According to this argument, "one cannot separate 'mitochondrial symptoms' from the symptoms related to the mitochondrial disorder-affected organs, including the central nervous system." Resp't Br., filed Aug. 21, 2012, at 3.

The undersigned cannot entertain the Secretary's argument. The Court's Opinion and Order has presented the issue as whether "Karl's neurological . . . symptoms . . . were manifested pre-vaccination, then Karl's case involves a

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The Court's framing of the issue, however, is not how the parties presented their cases before the remand. Consequently, there is relatively little evidence directly responsive to the Court's issue. From a transcript that runs more than 800 pages, each party identified only one passage in which an expert opines whether Karl was displaying neurological symptoms before vaccination.

The Secretary points to the following portion of cross-examination testimony as evidence in which Dr. Snodgrass opined about Karl's pre-vaccination neurological problems:

Q: . . . And in fact I believe you testified that his developmental delay began sometime in the fall of 2004. That would be – the neurologic system is a system of the body, correct?

A: It is.

Q: And the fact that he had developmental delay would indicate that he has some type of involvement of his neurologic symptoms – or his neurologic system.

A: His nervous system is abnormal, we can all agree on that.

* * *

Q: Well, he also has his muscle – musculoskeletal system involved, does he not?

A: I believe that is secondary to the central nervous system problem.

Tr. 416:10 to 417:22 (cited in Resp't Br., filed Aug. 21, 2012, at 3-4).

In contrast, the Palucks cited to this excerpt from Dr. Frye's testimony. With reference to the K.I.D.S. evaluation of Karl in October 2004, Dr. Frye testified:

A: . . . And the Vineland was used to look at his overall development, it can be used as an IQ, and we see that he actually was absolutely normal on the Vineland also without any delays. So really this points to the specific delays in gross motor, probably due to problems with muscle development, and the energy that the muscle needs, because of his mitochondrial disorder.

significant aggravation claim. . . . If not, then Karl's case involves a new-injury claim." This instruction is binding on remand. See Hanlon, 40 Fed. Cl. at 630.

Tr. 636:5-12 (cited in Pet'r Br., filed Aug. 28, 2012, at 3, and Pet'r Status Rep't, filed Sept. 4, 2012, at 1).

In sum, the basic dispute over whether Karl had symptoms of a neurological problem before vaccination is captured in those two passages. Dr. Snodgrass testified the Karl's gross motor delays identified in the fall of 2004 were "secondary to the central nervous system problem." Tr. 417:21-22. Dr. Frye's different view is that the gross motor delays were because of a problem "with muscle development, and the energy that the muscle needs, because of his mitochondrial disorder." Tr. 636:10-12.

These are the only passages in which the experts touch upon whether Karl displayed signs or symptoms of a disorder in his central nervous system before the vaccinations, although the record contains other relevant evidence, discussed below. After the parties filed briefs that were intended to identify evidence supporting their position regarding the onset of Karl's neurological problems, a status conference was held. The parties were informed that the quantum of evidence on this particular topic was relatively sparse. Thus, consistent with the Court's statement that the case was "remanded to the special master for further proceedings," the parties were invited to consider whether they wished to present additional evidence. Both parties declined. The Palucks stated "It would be a waste of resources in both time and money for this Court to open the record in the matter to receive additional evidence on mitochondrial disorders. . . . There is more than sufficient testimony and medical literature as a matter of record to permit this court to make a determination if this is a cause-in-fact injury case or significant aggravation injury case." Pet'r Br., filed Aug. 28, 2012, at 7.

As explained in the September 11, 2012 status conference, special masters may decide an issue even when there is relatively little evidence (or even no evidence) on the topic. King v. Sec'y of Health & Human Servs., No. 03-584V, 2008 WL 1994968, at *3 (Fed. Cl. Spec. Mstr. Feb. 7, 2008) (special masters "can always rule on a factual issue no matter how scanty the evidence is, even in the absence of *any* evidence. . . if there is no evidence, the factual issue simply is resolved against the party having the 'burden of proof'"). The special master's responsibility is to make findings of fact based upon the evidence and weighing that evidence. The evidence of record need only preponderate in one party's favor. It is not necessary for a party to submit a certain quantum of evidence to prevail. Under the preponderance of evidence standard, it is enough that the special master, as trier of fact, simply "'believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to

persuade the [judge] of the fact's existence.”” Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal., 508 U.S. 602, 622, 113 S.Ct. 2264, 124 L.Ed.2d 539 (1993)) (alterations in Moberly, further citations omitted).

Here, the evidence preponderates in the Secretary’s favor. Before explaining why it is more probable that Karl displayed problems in his central nervous system before the January 2005 vaccinations, the undersigned must acknowledge that the Palucks could be correct. It is certainly possible that Karl’s problem in gross motor skills was purely a problem in his muscles and not at all in his CNS. Based on this record, no one can say for sure. But, even in the absence of certainty, the evidence must preponderate one way or the other—either Karl’s gross motor problems originated with his CNS or they did not.⁹

Three reasons support a finding that Karl was manifesting problems with his CNS before 2005. First, indisputably, Karl was displaying poor muscle tone. The connection between CNS and muscle tone appears not to be particularly controversial, as Dr. Frye testified, in the context of explaining what tone is, “[t]he nervous system helps maintain tone.” Tr. 111:19-20¹⁰; see also Tr. 109:6-7 (Dr.

⁹ The outcome of this issue does not depend on how the burden of proof is allocated. The burden of proof determines which party prevails when the evidence is in equipoise. See Andrew Corp. v. Gabriel Electronics, Inc., 847 F.2d 819, 824 (Fed. Cir. 1988); Cook v. United States, 46 Fed. Cl. 110, 113 n.5 (2000); see also Director, OWCP v. Greenwich Collieries, 512 U.S. 267, 272-76 (1994) (discussing difference between burden of persuasion and burden of producing evidence). Here, the evidence is not in equipoise. The evidence preponderates in favor of the Secretary’s position.

¹⁰ At this point in his testimony, Dr. Frye had been asked to explain the significance of “truncal hypotonia,” a symptom that a neurologist detected in Karl in April 2005, months after the vaccination. Dr. Frye stated that truncal hypotonia “is suggesting that we have brain damage that is going on, or it also could be muscular damage, too. . . . It would be more damage to the nervous system.” Tr. 111:16-20.

Given this context, Dr. Frye’s testimony that “[t]he nervous system helps maintain tone” is viewed as supporting the limited proposition that problems in
(. . . continued)

Frye: “with increased tone, you think that there’s damage to the cortex of the brain or the white matter”).

Dr. Frye’s acknowledgement of a connection between low muscle tone and dysfunction in the CNS tends to make it more likely that Karl’s tone was due to a CNS disease. But, this general likelihood is not the only reason for finding that Karl exhibited neurological symptoms before his January 2005 vaccinations.

The second reason supporting a finding that Karl was displaying problems originating in his central nervous system in the fall 2004 was that Karl was having trouble with functions other than just his gross motor skills. According to the K.I.D.S. report that assessed Karl’s functioning, Karl had a problem with his expressive language. Exhibit 15 at 2-3.

While the Palucks steadfastly argue that before the January 2005 vaccinations, Karl “had normal central nervous system functioning,” Pet. Br., filed Aug. 28, 2012, at 7, this argument is not persuasive. The Palucks are overlooking the portion of the K.I.D.S. report that recommended Karl should receive developmental services “targeting his speech/language.” Exhibit 15 at 5.¹¹

A problem in expressive language tends, at least in the absence of other identified causes, to be considered a CNS problem.¹² Dr. Snodgrass’s testimony

tone sometimes originate in the nervous system. Tr. 111:19-20. Dr. Frye did not say all problems in muscle tone come from the nervous system.

¹¹ When questioned about this referral, Dr. Frye stated that the K.I.D.S. evaluators’ referral for speech therapy was “probably [a] more protective prophylactic measure[.]” Tr. 722:14-15. However, there is no evidence—other than Dr. Frye’s opinion—to support the assertion that the K.I.D.S. evaluators were not proposing a therapy intended to help Karl. The recommendation that Karl receive speech therapy is in line with his performance on the PLS-3 and Vineland, showing that Karl was 22 percent delayed in communication skills. A more detailed discussion of Karl’s expressive language in October 2004 is found in section IV.A.2 below.

¹² In one unrecorded status conference, the Palucks’ attorney suggested that Karl may have had a problem with his expressive language because he could have had a misshapen tongue. The Palucks have not offered this explanation in any of

(. . . continued)

alludes to this connection between expressive language and CNS. On direct examination, Dr. Snodgrass testified that prior to Karl's vaccination – in September and October of 2004 – his “development was abnormal in speech and language and both gross and fine motor function were impaired.” Tr. 328:5-6. On cross examination, Dr. Snodgrass testified that Karl’s “nervous system is abnormal” and that his pre-vaccination developmental delays indicated the involvement of his neurologic systems. Tr. 416:15-19.

Again, it should be pointed out that, as a matter of logic, it is possible that (a) Karl had gross motor delays exclusively because the mitochondria in his muscles (and only in his muscles) were not functioning, and (b) Karl had delays in his expressive language for unidentified reasons unrelated to his CNS. Conceivably, there could be two (or more) unrelated processes preventing Karl from developing normally in the domains of gross motor and express language. However, the question is what is more likely? It seems much more likely that Karl’s mitochondrial defect was already starting to affect his central nervous system before the January 2005 vaccinations. Mitochondrial defects can impair the functioning of organs with a high need for energy, such as the central nervous system. Exhibit E (Haas) at 1327.

Finally, and least importantly, the Palucks and Dr. Frye made evidentiary admissions that are consistent with a finding that Karl’s case is one for significant aggravation. For example, the Palucks’ October 17, 2008 Amended Petition stated that they allege that the “vaccines given on January 19, 2005 caused a significant aggravation of Karl’s underlying mitochondrial disorder, leading to alterations in his brain development and subsequent neurodevelopmental regression.” Amended Pet., filed Oct. 17, 2008, at 2. The Secretary’s post-remand brief specifically cited this pleading, Resp’t Resp., filed June 8, 2012, at 4-5, and the Palucks have not explained why they should not be held to their attorney’s statements. See Pet’r Br., filed Aug. 28, 2012.

Similarly, the Secretary cited a portion of Dr. Frye’s testimony that supports the Secretary’s view that Karl’s case is one of significant aggravation. Dr. Frye stated: “I believe that [it] is more likely than not that the vaccines received on January 19, 2005, significantly changed the course of Karl’s development by

their written briefs and the Palucks have not identified any evidence that supports a finding that Karl’s developmental delay in regard to expressive language was based upon a structural problem.

significantly exacerbating an under[y]ing mitochondrial disorder.” Resp’t Br., filed Aug. 21, 2012, at 2 (citing Tr. 53:9-12).¹³

Dr. Frye’s use of the term “significantly exacerbating” in his testimony and the Palucks’ use of the term “significant aggravation” in their amended petition further support a finding that Karl’s case should be characterized as one of significant aggravation, although these comments are not dispositive by themselves. In the Vaccine Program, special masters typically do not strictly hold petitioners to their pleading.¹⁴ Similarly, not too much weight is given to Dr. Frye’s isolated statement referring to “significantly exacerbating.” On the other hand, to the extent that the amended petition and Dr. Frye’s testimony have relevance, they weigh, slightly, on the side of significant aggravation.

For these reasons, the preponderant weight of the evidence favors finding that Karl was displaying neurological problems before vaccination.¹⁵ Thus, according to the structure set by the Court’s Opinion and Order, Karl’s case is properly analyzed as presenting a claim for significant aggravation.

¹³ In the same paragraph of the Secretary’s brief, she cites other portions of Dr. Frye’s testimony for the proposition that “Dr. Frye often characterized Karl’s post-January 2005 condition in terms that suggested a connection to all his symptoms.” Resp’t Br., filed Aug. 21, 2012, at 2. However, in the cited portions of Dr. Frye’s testimony, he seems to be comparing Karl’s condition in April or June 2005 to Karl’s condition in January 2005, not Karl’s condition in October 2004.

¹⁴ In traditional litigation, parties are bound by their pleadings. See, e.g., Best Canvas Prods. & Supplies, Inc. v. Ploof Truck Lines, Inc., 713 F.2d 618, 621 (11th Cir. 1983) (stating that as a general rule “a party is bound by the admissions in his pleadings”) (citations omitted).

¹⁵ The undersigned has also considered the relative experience of Dr. Frye and Dr. Snodgrass. Both have some experience with mitochondrial disorders, but neither has extensive experience. For Dr. Frye’s background in mitochondrial disorders, see Tr. 42:25 to 46:20, 210:16 to 213:2. For Dr. Snodgrass’s experience, see Tr. 250:11-14, 396:4 to 400:12, 495:2-4, 554:13-55:7. Thus, this factor does not contribute to accepting or to rejecting either Dr. Frye’s opinion or Dr. Snodgrass’s opinion.

IV. Significant Aggravation

The elements of an off-Table significant aggravation case were stated in Loving v. Secretary of Health & Human Servs., 86 Fed. Cl. 135 (2009).¹⁶ There, the Court blended the Althen test, which defines off-Table causation cases, with a test from Whitecotton, which concerns on-Table significant aggravation cases. The resultant test has six components. These are:

- (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 constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; see also Opinion and Order, 104 Fed. Cl. at 468, n.14 (citing and quoting the Loving test).

Since Loving was decided, the Federal Circuit has explained that possible alternative causes may be considered as part of a petitioner's *prima facie* case. See Stone v. Secretary of Health & Human Servs., 676 F.3d 1373, 1380 (Fed. Cir. 2012). To maintain clarity in parts of the analysis, the possibility of alternative causes is set out in a separate section below. See section V.

Of the six parts to the Loving test, the December 14, 2011 decision addressed factors four through six because those elements overlap with the Althen test. Although the Court accepted this method of analysis, the Court vacated the decision with respect to each of the Althen elements. The Court's analysis of factors four through six is discussed extensively in the context of the particular element. However, factors one through three have not been specifically analyzed

¹⁶ After remand, the Federal Circuit approved the Loving six-prong test as accurately setting forth the elements of petitioners' case. W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013).

in either the December 14, 2011 decision or the Court's Opinion and Order. Hence Loving factors one through three begin the analysis.

A. Loving Prong 1: What was Karl's Condition Prior to Administration of the Vaccine?

The first step in the Loving test is to define Karl's condition before he received the vaccinations at issue. An overarching problem is that Karl was born with a mitochondrial defect, although the doctors treating Karl before the vaccinations did not know of this defect.

The parties agree that Karl's mitochondrial defect was affecting his development before vaccination. The Palucks maintain that the mitochondrial defect was isolated to Karl's muscles and this mitochondrial defect caused Karl to have delays in his gross motor development that was recognized in October 2004. See Pet'r Br., filed Aug. 28, 2012, at 3 ("Dr. Frye explained that the delays noted in this October 2004 evaluation [referring to the K.I.D.S. assessment] were secondary to problems with Karl's muscle development and energy needs because of his undiagnosed medical disorder."). Thus, the Palucks recognized that the mitochondrial disorder was impairing Karl's health, but disputed linking the mitochondrial disorder to Karl's CNS.

The Secretary agreed that Karl's mitochondrial disorder was already being manifested in the fall 2004. Resp't Br., filed Aug. 21, 2012, at 1 ("Karl's mitochondrial symptoms, including neurological symptoms, manifested before his receipt of his January 2005 vaccinations."). As discussed in the preceding section, a preponderance of evidence supports the finding that the mitochondrial problem impaired the functioning of Karl's CNS.

To determine the state of Karl's condition prior to vaccination, it is necessary to examine his medical records and the experts' testimony on various aspects of his health and development. The following sections discuss his illnesses and immunologic responses, expressive language skills, and the extent of his gross motor problems. On the second and third topics, the experts have some disagreements.

1. Illnesses and Karl's Immunologic Responses

As the Court stated "[d]uring this same time period [before vaccination], Karl began manifesting two medical problems that would appear repeatedly from

October 2004 to July 2005: otitis media and erythema multiforme.” Opinion and Order, 104 Fed. Cl. at 462 (footnotes deleted without notation). Exhibit 3 at 38, 57-62. The erythema multiforme indicates that Karl’s immune system was activated. Tr. 98:8-12, 295:2-14.

On October 14, 2004, Karl was examined by Dr. Amy E. Oksa, who recorded an impression of bilateral otitis media, viral exanthema, and left conjunctivitis. Dr. Oksa prescribed Amoxicillin for the ear infection, Gentamicin ophthalmic solution for the conjunctivitis, but no specific treatment for the rash. The Palucks were encouraged to return to the clinic in “two to three weeks for recheck [of the rash] and sooner if needed.” Exhibit 3 at 57.

On November 8, 2004, Karl was seen by Dr. Donna J. Mumert at the Dickinson Clinic. The physician reported that Karl “has a history of otitis media. Mom states that she’s not sure that he’s getting better and would like to have his ears rechecked.” Karl’s mother also reported that he had been “fussy over the past couple of days.” Dr. Mumert recorded an impression of left otitis media and prescribed Zithromax to be administered daily for five days. She recommended that Karl be rechecked in one week or sooner. Exhibit 3 at 58.

On November 15, 2004, Karl returned to the Dickinson Clinic and was examined by Dr. Oksa, who recorded that Karl presented for an ear recheck, having “had bilateral otitis media initially treated with amoxicillin one month ago and then treated with Zithromax one week ago. He currently seems to be doing well.” Ms. Paluck also recounted that Karl “still has been fussy and irritable.” Dr. Oksa’s impression was that the otitis media had resolved. Under “Plan,” the report notes “Flu shot today.” Exhibit 3 at 59.

On December 4, 2004, Karl visited the Dickinson Clinic for a recheck and was examined by Dr. Mumert. The report states that Karl

was on Zithromax two weeks ago for an ear infection. He did have an ear recheck following this. His ears were clear. However, mom states he has been fussy over the past couple of days. . . . Mom states that for the last week he has been irritable and not his usual self. He has not had any fevers. No diarrhea. He is otherwise healthy and well.

Exhibit 3 at 60. After examining Karl, Dr. Mumert recorded an impression of bilateral otitis media. She also noted that Karl’s skin was “[n]ormal with no

exanthem.” Id. She prescribed Omnicef for 10 days and recommended that Karl be rechecked in two weeks or sooner. Id.

Karl returned two weeks later, on December 11, 2004, to be examined by Dr. Oksa. In her report, Dr. Oksa wrote that “Karl presents today for evaluation of skin lesions on his arms and legs. Patient has had these for greater than one week. Of note, he had a similar type rash October 14, 2004, when evaluated for bilateral otitis media and conjunctivitis.” Exhibit 3 at 61. Dr. Oksa continued:

Mother states that this rash went away, but developed again about a week ago. . . . The fussiness was better, but now has worsened over the last couple of days. He also developed a very slight papular rash on trunk earlier this week, but it was much different than the extremity rash and has pretty much gone away. It was not urticarial. Mother could barely perceive it. It had been noticed by the day care provider. The Omnicef was stopped . . . three days ago, secondary to more of the rashes.

Id. Dr. Oksa’s examination revealed “several 0.5 to 1.0 centimeter areas of erythema which are slightly raised, but nontender. These are present mostly on the distal extremities, but there are also a couple of lesions on the proximal upper extremities.” Id. She observed that “[s]ome are more purplish in appearance. No petechiae or purura noted.” Id. Dr. Oksa recorded an impression of “[r]esolved otitis media” and “[p]robable erythema multiforme secondary to viral illness.” She prescribed Orapred and recommended a return to the clinic if the symptom persisted or worsened. Id.

On December 22, 2004, Karl presented at the Dickinson Clinic for a recheck of his rash. Dr. Oksa recorded that Karl’s “[m]other states that the spots almost totally resolved. The only lesions that were left were slightly bluish resolving lesions. After the Orapred was finished the red spots came back and now . . . are worse than . . . before.” Exhibit 3 at 62. Dr. Oksa reported “[a]pproximately 1.0 centimeter erythematous, slightly raised vesicular lesions on extremities, more on the distal lower extremities than proximal and mostly on the distal upper extremities. The rest of the skin is spared.” Id. Her impression was a recurrent, nonspecific rash. Dr. Oksa’s plan was to “discuss patient with Dr. Cornatzer, Dermatology, and proceed with whatever recommendations he has.” Id.

The Palucks brought Karl to Dr. Cornatzer, a dermatologist, on December 27, 2004. Dr. Cornatzer obtained a biopsy from Karl's left arm. The results of the biopsy were consistent with the diagnosis of erythema multiforme. See exhibit 9 at 1-3.

Karl's erythema multiforme presents a potential alternative cause for Karl's neurodegeneration (as the Palucks have defined Karl's neurodegeneration). Although Dr. Frye acknowledged that Karl suffered from erythema multiforme before vaccination, this condition did not affect Dr. Frye's opinion. See Tr. 626:19 to 628:6 (redirect). However, Dr. Snodgrass questioned the consistency of Dr. Frye's position. Dr. Snodgrass queried if Dr. Frye were correct that Karl's neurodegeneration started when Karl's immune system was activated, why didn't the erythema multiforme start that process? In Dr. Snodgrass's view, if Dr. Frye were correct on his theory, the erythema multiforme (and not the vaccinations) could have caused the aggravation. See Tr. 357:16 to 358:17 (direct examination); see also Tr. 443:16-19 (cross examination). Resolution of this question is not necessary because, as explained below, Karl did not significantly decline in the weeks immediately following January 19, 2005, when he both received a set of vaccinations and suffered another bout of erythema multiforme.

2. Expressive Language

One point of departure between the experts regarding Karl's pre-vaccination condition is his expressive language. The primary source of information about Karl's ability to use language is the K.I.D.S. evaluation in October 2004.¹⁷ Karl's language was evaluated using three tests, the Bayley Scales of Infant Development 2nd Edition, the Preschool Language Scale-3 ("PLS-3"), and the Vineland Adaptive Behavior Scales. Exhibit 15 at 2.

Bayley. On this test, Karl's "MDI" was 91.¹⁸ An MDI score of 91 is the age equivalent of eight months. Since Karl was a few days past nine months old at

¹⁷ Dr. McDonough's January 19, 2005 evaluation adds additional information about Karl's language. This report is discussed in the following section.

¹⁸ In this context, "MDI" probably means "mental development index." Medical Abbreviations (15th ed. 2011) at 204.

the time of the evaluation, this represented a delay of 11 percent. Nevertheless, he was classified as “Within Normal Limits.” Exhibit 15 at 2.

Vineland. In the “Communication Domain” of the “Adaptive Behavior Composite” for the Vineland, Karl’s standard score was 94. This placed Karl in the 34th percentile with an age equivalency of 7 months. The amount of his delay in communication was 22 percent. Exhibit 15 at 3.

PLS-3. Karl’s performance on the Vineland’s Communication Domain was quite similar to his score on another standardized test the K.I.D.S. evaluators gave to him, the Preschool Language Scale-3. “The PLS-3 evaluated Karl’s ability to use language (language expression) and understand language (auditory comprehension).” Exhibit 15 at 2. For “Expressive Communication,” Karl’s standard score was 101, which placed him in the 53rd percentile. His age equivalent was “7 months,” again making him 22 percent delayed. Id. at 3. Dr. Snodgrass briefly addressed the PLS-3, agreeing with petitioners’ counsel that it placed Karl at the seven month level. Tr. 459:20 to 460:1.

In Dr. Frye’s opinion, Karl’s “language was right at the average.” Tr. 100:5. Dr. Frye based his opinion on the PLS-3. Dr. Frye stated that Karl’s “total language standardized score was 96. The average is 100, but 96 is very close to 100 on these scales, and so he was very close to normal as far as his language.” Tr. 100:5-8.

In this context, Dr. Frye also discussed the result of Karl’s performance on the Vineland Adaptive Behavior Scales. Dr. Frye stated, “As far as what normal development would be considered, that his delays were most prominently gross motor delays, maybe a little bit of fine motor delays, but cognition, language was absolutely normal.” Tr. 101:8-11; see also exhibit 15 at 3 (reporting results of Vineland).

Additionally, Dr. Frye testified that he viewed the PLS-3 as unnecessary because Karl passed the Denver II test¹⁹ at one year of age. Dr. Frye explained that the Denver test “is a screening test . . . to tell you to go for more specific tools such as the PLS or the PDMS. And really more specific tools like [these] shouldn’t really necessarily be used unless you fail some screening tests.” In this case Karl

¹⁹ See sub-section IV.A.3.b., below, for a description of the Denver II and Karl’s results on the test.

“actually passed the Denver[,]” which “suggests that he doesn’t need any of those tests at one year of age.” Tr. 822:17 to 823:4.

When asked whether Dr. Frye was correct in assessing Karl as “right at the average” in his language, Dr. Snodgrass said that Dr. Frye was not correct. Dr. Snodgrass explained why he thinks that Karl’s language was not at the average. Dr. Snodgrass testified that

the evaluation included a number of things and it included the fact that Karl did not seem to respond to ‘no’. Now no is a pretty elementary communication. And he did not mime or copy sounds made by others. Before we can speak normally, small babies will make noises similar to a noise which their caretaker is making.

Tr. 329:5-12. Dr. Snodgrass did acknowledge that Karl scored within normal limits on the Bayley test. Tr. 459:16-19.

When Dr. Snodgrass was asked whether Dr. Frye’s statement from transcript page 101 that “cognition language was absolutely normal” was true, Dr. Snodgrass said, “I think if we refer to Exhibit 15 we’d have to say no that’s not correct.” Tr. 329:16-17.

During redirect, Dr. Frye essentially repeated his opinion that the October 2004 K.I.D.S. evaluation showed that Karl’s “language was completely normal.” Tr. 636:1-2. Dr. Frye also stated that “he actually was absolutely normal on the Vineland also without any delays.” Tr. 636:7-8. The Palucks’ attorney did not ask Dr. Frye to address Dr. Snodgrass’s testimony on page 329 of the transcript.

The undersigned, however, requested that Dr. Frye address the difference in his opinion expressed on page 99 of the transcript and Dr. Snodgrass’s opinion from page 329. Dr. Frye was referred to four skills relating to language that the K.I.D.S. evaluators said that Karl could not perform. Dr. Frye was told that Dr. Snodgrass pointed to some of these deficiencies as supporting Dr. Snodgrass’s opinion that Karl was delayed in language. Dr. Frye responded: “But I don’t think that’s correct because . . . the objective standardized test put him absolutely in the average range.” Tr. 722:9-11.

Dr. Frye also questioned the consistency of the K.I.D.S. evaluation. Dr. Frye noted that one of Karl’s listed weaknesses was not communicating with

gestures. However, one of Karl's identified strengths was "gestur[ing] for 'I want.'" See Tr. 723:9-25; see also exhibit 15 at 3, 5.

There was a brief rejoinder from Dr. Snodgrass when he testified later that day. Dr. Snodgrass stated that "things like not responding to no no was significant, it was more than just a minor trivial thing." Tr. 787:11-13.

When the K.I.D.S. evaluators identified problems with Karl's gross motor skills and expressive language, they referred him for therapy "targeting his speech/language, gross motor, and the delays in fine motor related to low muscle tone." Exhibit 15 at 5. If the Palucks accepted this referral for treatment, then the notes are not contained within exhibit 15.

While the Palucks argue that Karl's language development was normal, as measured by the various tests performed in October 2004, it seems unlikely that the evaluators would have referred Karl to therapy targeting his speech and language if this were the case. Accordingly, the preponderant weight of the evidence favors finding that Karl's language development was delayed prior to his vaccination.

3. Extent of Gross Motor Problems before Vaccination

Another area of difference between Dr. Frye and Dr. Snodgrass concerns Karl's physical function on the day he received his vaccinations, January 19, 2005. In short, Dr. Frye saw Karl as relatively well, except for some motor delay. In contrast, Dr. Snodgrass's viewed Karl as worsening.

Dr. Snodgrass's opinion rests upon Dr. McDonough's records from appointments on December 27, 2004, and January 19, 2005. Thus, those two notes are detailed below. Following those summaries, the competing perspectives of the experts are set forth.

a) Developmental Status on December 27, 2004

During the appointment during which Dr. Cornatzer biopsied Karl's rash, Dr. Cornatzer recommended that Dr. McDonough see Karl because Karl had been pulling on his ears. See exhibit 3 at 5. This was on December 27, 2004, 23 days before the date of vaccination. See exhibit 23 at 7-8. Dr. McDonough recorded a developmental history that "Karl is rolling over. He tries to crawl, he has several words that he says." In Dr. McDonough's assessment of Karl's neurologic system,

he records the following good traits about Karl: "normal muscle tone. There is no ankle clonus. Deep tendon reflexes appear to be symmetrical. He has good head control and fairly good truncal control." On the other hand, Dr. McDonough also states Karl "is not pulling himself to stand or crawling yet." Dr. McDonough assessed Karl as having "possible mild gross motor delay," but did not refer Karl for therapy or otherwise mention whether Karl was receiving services through the K.I.D.S. program. Dr. McDonough intended to check Karl at his next visit in one month. Exhibit 3 at 5-6.

b) Developmental Status on January 19, 2005

The next appointment, a well-baby visit to assess Karl at one year of age, occurred on January 19, 2005. In the history of present illness section, there is a notation that Karl is not standing. The HPI section also states "recheck rash." Exhibit 5 at 62.

For the "Growth & Development" section, there is a circle around "Roll Over" and "Babbles," skills associated with a six month old. Next to the words "Sit well" and "Pull to Stand," abilities associated with an eight month old, is the hand-written notation "not." For nine months category, the form lists "Crawl" "Wave bye" "Dada-Mama." Of these three, only "Crawl" is circled with handwriting saying "4 point." For the 11-12 months category, the form lists "Cruise / Roll Ball," "Use cup / Pincer" and "1-3 words." None of these items is circled. Beside the "Use cup / Pincer" skill is handwriting noting "not yet." An additional handwritten note in another portion of the form states "doesn't hold cup well." Handwriting next to "1-3 words" is difficult to decipher, but appears to say "no words." Exhibit 5 at 62.

Another assessment of Karl's abilities is presented on a Denver II ("Denver") screening form. Exhibit 5 at 35. (The Palucks and Dr. Frye filed a blank Denver screening form to assist in understanding the typical development, because Karl's form is faded, making it difficult to read. See exhibit 38.) The Denver evaluates four different domains (personal/social, fine motor adaptive, language, and gross motor), which are distributed along the screening form's vertical axis. Across the form's horizontal axis, top and bottom, are marks designating the age of the child, from birth to 6 years of age. During an evaluation, the evaluator aligns a ruler with the marks printed on the top and bottom of the form corresponding to the child's age and draws a vertical line through the form. This line intersects with specified age-appropriate skills printed on the form in each of the four domains. Dr. Frye explained how the form is used.

If you look in the upper left hand corner you see what seems to be a scale, it says percentage of children passing and it goes from 25 to 50 to 75 to 90. . . .

This is important because as long as this line that's drawn . . . is within that shaded bar we know that it's within normal limits. . . .

[T]he way we use the Denver . . . we go through the four different areas, that is personal/social, fine motor adaptive, language, and gross motor, and we ask whether a child can do these skills or can't do these skills. And if th[e] line that we've drawn is outside one of those boxes and the child can't do that [skill], we get concerned.

. . . the way we notate this usually is if the child can do an activity we put P for pass, if they can't we put F for fail. . . .

* * *

. . . if their chronological age passes through that box that means they should have developed or be developing that skill. It's not until their chronological age actually passes the box that you say that they should have done it and they're not or that they've actually failed that developmental milestone.

Tr. 631:10 to 633:22.²⁰

Within the personal - social domain, Dr. McDonough assigned Karl three "P's" (for passing) and two "F's" (for failing). The passing abilities were "initiate activities," "play ball with examiner," and "indicate wants." The failing skills were "wave bye-bye" and "play pat a cake." For both these activities, more than 75 percent of children can do them by 12 months. On the other hand, "initiate activities" and "play ball with examiner" seem to be activities performed by less than 75 percent of children.

Within the domain of "fine motor - adaptive," there is one "P" that is near two different skills, "bang 2 cubes held by hands" and "thumb finger grasp." Both of these activities can be accomplished by 99 percent of children at 11 months.

The next domain is "language." Dr. McDonough has an "F" for "one word" and a "P" for "dada-mama specific." The "dada-mama specific" skill is something

²⁰ Dr. Snodgrass did not disagree with Dr. Frye's explanation. See Tr. 799:11-17 ("Well I think he is reiterating what the developers of the Denver would say.").

approximately 75 percent of children can accomplish by approximately 11 months. For the “one word” skill, about 50 percent of children can do this by 12 months, with 75 percent of children speaking one word at 14 months.²¹

The final domain is “gross motor.” There are two “P’s” for “stand holding on” and “pull to stand.” Approximately 75 percent of children can pull to stand at approximately 9 months and approximately 99 percent can pull to stand at approximately 10 months. Karl’s form also has three “F’s” in gross motor. Of these three skills that Karl was not displaying, the most basic step is “get to sitting.” The normal values for “get to sitting” is about the same as “pull to stand,” with about 75 percent of children getting to sitting at nine months and 99 percent getting to sitting at 10 and 1/2 months. The other two skills in the gross motor domain marked with F’s are “stand 2 secs,” and “stand alone.” There was no mark for two skills that fewer than 50 percent of children can do at 12 months: “stoop and recover” and “walk well.”

There are some slight inconsistencies in the recording of Karl’s abilities between the two forms. For example, on the form from Dr. McDonough’s office, the entry for “Dada-Mama” around 9-10 months is not circled. Exhibit 3 at 3. Yet, on the Denver form, Karl got a “P” for “dada-mama specific.” Similarly, Dr. McDonough did not circle, but wrote the word “not” next to “Pull to stand” under 7-8 months, whereas there is a P on the Denver form next to “pull to stand.”

Dr. McDonough’s office form also has a section in which the pediatrician can report the results of a physical examination. Most systems were “WNL” (within normal limits). There are two exceptions. First, the entry for “Hips” is checked WNL, but there is a handwritten notation saying “got [illegible] ↓ROM.” See Tr. 825:9-19, 829:12 to 831:6, 331:6 (interpreting notation to indicate a decreased range of motion). Second, the entry for “Neuromuscular” is checked as ABN (abnormal). The handwriting says “muscle tone ↑+ upper.” The entry appears to continue on the next line, saying “lower extremities.” A third line reads “2 Beats clonus R [illegible]. A fourth line reads, perhaps, “inconsistent.”

Dr. McDonough’s assessment includes “gross motor delay” and “recurrent erythema multiforme.” The plan was an “early development referral [to] Dickinson.” The Dickinson Clinic offered “> [greater] available PT OT [physical

²¹ Dr. Frye explained that doctors usually do not count a child’s speaking “dada” or “mama” as a spoken word. Tr. 748:4-13.

therapy and occupational therapy] services.”²² Dr. McDonough also prescribed Zithromax. He wanted Karl to return in 3 months. Exhibit 3 at 3.

c) Testimony

The testifying experts came to different conclusions about Karl’s functioning as of January 19, 2005. Dr. Frye’s initial direct testimony discussed Karl’s status on the date of vaccination relatively cursorily. The extent of the dialog between the Palucks’ attorney and Dr. Frye was:

Q: Then if we move to January of 2005 at his 12-month and four days past his 12-month birthday, he received the MMR, PCV7, and Varicella. At that evaluation for those – and at the receipt of those vaccines, his pediatrician did note that he was going to refer Karl for possible, again, motor delay.^[23]

A: Right.

Q: And specifically those gross motor delays were as you were just describing. He wasn’t able to sit totally unsupported, and he was not yet crawling or pulling himself to a stand.

A: Exactly.

Tr. 102:16 to 103:4. At this point, the Palucks’ attorney begins questioning Dr. Frye about Karl’s fevers following the vaccinations.

In Dr. Snodgrass’s preliminary²⁴ direct testimony, he also briefly discussed Karl’s status in January 2005. Dr. Snodgrass stated that Karl worsened between

²² In a later record, Dr. McDonough specified that on January 19, 2005, he referred Karl for “physical and occupational therapy in Dickinson” and recommended a “stimulation program and ongoing tracking” with “Badland Human Services.” Exhibit 3 at 7.

²³ Although counsel’s question says that Dr. McDonough was referring Karl for “possible” motor delay, Dr. McDonough referred Karl for motor delay. Exhibit 3 at 3. Unlike Dr. McDonough’s December 27, 2004 report, the January 19, 2005 report does not characterize Karl’s gross motor delay as “possible.”

²⁴ The first day of the hearing was March 22, 2010. During that session, the Palucks’ attorney requested that Dr. Snodgrass testify on direct examination before

(. . . continued)

his visits with Dr. McDonough on December 27, 2004, and January 19, 2005. In the earlier appointment, Dr. McDonough recorded that Karl “says words.”” Tr. 257:14 (quoting exhibit 3 at 5). However, in the next month, Dr. McDonough “says, ‘No words, doesn’t sit well.’” Tr. 257:14-15 (quoting exhibit 5 at 62). To Dr. Snodgrass, “something was changing in that relatively short interval, a bit less than a month.” Tr. 257:18-19.

When the hearing resumed, Dr. Snodgrass returned to the differences in Karl between December 2004 and January 2005. Dr. Snodgrass commented that in December 2004, Dr. McDonough said that “Karl doesn’t pull to stand or crawl. That his development is abnormal but that his tone, muscle tone, is normal.” Tr. 330:22-24; accord exhibit 3 at 5. To Dr. Snodgrass, Dr. McDonough’s finding that Karl has normal muscle tone in December 2004 is important because on January 19, 2005, Dr. McDonough found that “Muscle tone of the extremities and the back is up or increased and there’s ankle clonus on one side.” Tr. 331:7-9.²⁵ In Dr. Snodgrass’s view, Karl was worse in January than he was in December: “These are new findings which were not present in December. This [ankle clonus] is a positive finding if you have abnormal tone, whereas beforehand, the findings were simply that Karl could not do things which the average child would do at that age.” Tr. 331:10-14.

Dr. Frye did not rebut Dr. Snodgrass’s opinion that between December 2004 and January 2005, Karl worsened. Dr. Snodgrass pointed to two deteriorations. First, Karl went from “says words” to “no words.” Second, Karl went from “normal muscle tone. . . . [with] no ankle clonus,” exhibit 3 at 5, to “muscle tone [increased]” with “2 beats clonus” on his right side, exhibit 5 at 62. Thus, there is preponderant evidence that in two areas of development – gross motor and

the Secretary cross-examined Dr. Frye. This request was denied and the hearing proceeded in a more traditional format with cross-examination of Dr. Frye immediately following his direct examination. See Tr. 134:1 to 141:2. The duration of Dr. Frye’s testimony and Dr. Snodgrass’s travel commitments limited Dr. Snodgrass’s direct testimony on March 22, 2010, to a short amount of time.

²⁵ Dr. Snodgrass also interpreted Dr. McDonough’s handwriting as saying that Karl had a “decreased range of hip motion.” Tr. 331:6. This portion of Dr. McDonough’s record is not easily deciphered.

expressive language – Karl was worse in January than he was the previous month.²⁶

Dr. Snodgrass's opinion that Karl was deteriorating in December 2004 accords with statements made by Ms. Paluck during Karl's hospitalization in July 2005. When Karl was hospitalized, Ms. Paluck told four people (Dr. Oska (a physician at St. Joseph's Hospital); Molly Eastman (a nurse practitioner, working

²⁶ Some testimony compared Karl's gross motor ability in January 2005 to his gross motor ability in October 2004. Dr. Frye stated that Karl's gross motor ability in October 2004 was the equivalent of a four month old. Since Karl was nine months old in October 2004, the amount of delay was five months. Tr. 639:6-9. In January 2005, Karl's gross motor development was between nine and ten months, making his delay two to three months. Tr. 639:13 to 640:6. So, in Dr. Frye's opinion, Karl's gross motor functioning had improved between October and January because "he was a little bit less delayed." Tr. 638:24.

Dr. Snodgrass stated that attempting to give Karl an overall level of functioning was not helpful.

I've got a problem with the whole Denver concept of reducing gross motor to X months. Karl had asymmetrical motor performance. There were a number of areas where his performance was quite bad. . . .

So the problem is you can take a thing he does badly and a thing he does well and average them, but that doesn't really give you a useful answer. In other words I wouldn't want to reduce his gross motor impairment to a single area[,] but I would say his gross motor performance was bad, I'd certainly say that.

Tr. 802:18 to 803:6; see also Tr. 458:21-24 (Dr. Snodgrass: "What we have for Karl is that in some areas his problem was greater than in others. So trying to reduce him to a single age equivalent of eight months is, I believe, misleading.").

Comparing Karl in October 2004 to Karl in January 2005, while interesting, is not very illuminating. The K.I.D.S. testing was a "very good and extensive evaluation." Tr. 99:2 (Dr. Frye); accord Tr. 328:20-24 (Dr. Snodgrass agreeing with Dr. Frye's testimony on transcript page 99). Training is required to administer the standardized tests given to Karl as part of the K.I.D.S. testing. Tr. 821:17-21 (Dr. Frye); see also Tr. 786:10-15 (Dr. Snodgrass). In contrast, the Denver screening test "is a quick screening test, it's not a detailed evaluation." Tr. 786:8-9.

with Dr. Frost); Dr. Pierpont (a geneticist); and Dr. Moertel (a hematologist)) that Karl's problems started in the fall 2004. See Tr. 360:3 to 367:2 (Dr. Snodgrass) (citing exhibit 6 at 62-65; exhibit 11 at 225, 229-32, 234; and exhibit 11 at 46). Two of those reports say that Karl began to lose milestones at 11 months.

Since Ms. Paluck was recounting in July 2005 Karl's status in December 2004, her recollection is not truly contemporaneous. See Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 539 (2011) (discussing "contemporaneous"), aff'd without opinion, No. 12-5152 (Fed. Cir. May 7, 2013). On the other hand, Ms. Paluck was providing her statement when she was seeking treatment to solve Karl's medical problem and her statement was not made when she was anticipating litigation. Furthermore, as Dr. Snodgrass testified without any contradiction, the medical personnel who created these records obtained the history from Ms. Paluck independent of each other and they are consistent with each other. Thus, these histories are entitled to some consideration, see Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993), even if they are not dispositive by themselves. See Tr. 646:6-7 (Dr. Frye stating that he "rel[ies] very heavily on care giver information").

Overall, by January 19, 2005, Karl had problems in his CNS. His pediatrician diagnosed him with gross motor delays, which had worsened in the preceding three weeks. Karl was also having problems with his language. Finally, Karl was recovering from the most recent episode of erythema multiforme.

B. Loving Prong 2: What is Karl's Current Condition (or His Condition Following the Vaccination, if Also Pertinent)?

The second part of the Loving test is to discuss "the person's current condition (or the condition following the vaccination if that is also pertinent)." While both periods are included in the Court's test, an analysis of Karl's most current condition is not possible, as the Palucks have not filed recent medical records.²⁷ Accordingly, the analysis under this prong will focus solely on Karl's health in the months following his vaccination.

²⁷ The Palucks' counsel, without submitting any medical records, presented some information about Karl's health during the April 10, 2013 oral argument on the second motion for review. She stated that Karl was recently hospitalized but has returned home. He requires a ventilator to breathe and his parents have implemented a do not resuscitate order. He remains unable to perform basic life

(. . . continued)

The December 14, 2011 decision discussed Karl’s post-vaccination status as part of the second Althen prong. That decision concluded that between September 2004 and July 2005, Karl’s developmental progress was “not linear.” Decision, 2011 WL 6949326, at *23. The Court’s Opinion and Order vacated this aspect of the December 14, 2011 decision primarily because it failed to discuss records of a chiropractor whom Karl was seeing. Opinion and Order, 104 Fed. Cl. at 480.

For ease of organization, Karl’s history is divided into periods, roughly corresponding to the source of information about Karl.

1. Daycare Records

The first post-vaccination record created contemporaneously with the events being described in it is a record from Karl’s daycare.²⁸ For January 21, 2005, there is an entry stating that “Deb [presumably a staff member at FunShine Express] talk [sic] to Rhonda [Karl’s mother] about chiropractor.” The daycare record also states that Karl had a temperature of 101.5 degrees. Exhibit 22 at 1.

A daycare staffer made additional entries on January 24, 25, and 26, 2005. On these three days, Karl was recorded as being “fussy.” However, there is no notation or other indication that Karl had a fever on any of those days. On January 28, 2005, Karl is again recorded as being “very fussy,” but the caregiver also states that Karl had a fever of 101.3. Exhibit 22 at 2.

sustaining activities such as eating and swallowing. He receives nutrition through a feeding tube. See Oral Arg. Tr., April 10, 2013, at 34:16 to 35:20.

²⁸ The Palucks filed two pages of records from Karl’s daycare provider, FunShine Express. These two pages contain entries beginning on January 6, 2005 and ending on February 8, 2005. Exhibit 22.

During the earlier phase of the case, the undersigned ordered the Palucks to produce other records from Karl’s daycare. Order, filed July 22, 2011. The Palucks filed a status report, stating “there are no other daycare records to be obtained and, therefore, none to be submitted.” Pet’r Status Rep’t., filed Aug. 22, 2011.

The experts discussed the significance of the fever on these two days and the other symptoms, such as tiredness, that the daycare providers recorded.²⁹ Dr. Frye

²⁹ The Court questioned whether it was appropriate to find that Karl had fever only on these two days. The Court stated “[r]easoning from . . . omissions to a positive postulate is always questionable.” Opinion and Order, 104 Fed. Cl. at 476, n.27 (citations and quotation marks omitted).

The finding that Karl did not have a fever on days other than January 21 and January 28, however, is consistent with how the parties presented their cases. In an October 27, 2009 status conference, the parties discussed the extent of Karl’s fevers. The undersigned had inquired if a hearing to determine facts about Karl’s condition were needed. The Palucks’ attorney represented that the presence of a fever does not make a difference to Dr. Frye’s opinion because he saw evidence of an encephalopathic process whether or not Karl had a fever. Ultimately, in the October 27, 2009 status conference, the parties agreed that although there may be a genuine dispute about whether Karl’s fevers were “high,” this was a non-material fact. In light of this agreement, the undersigned did not order a fact hearing.

Although the October 27, 2009 status conference was not recorded, the extent of the agreement was memorialized at the beginning of the hearing. Tr. 8:18-25. Although both counsel commented upon the undersigned’s description of the fever issue, the attorneys did not argue that Karl had a fever on days other than January 21 and January 28. Tr. 11:19 to 12:18.

In their post-hearing brief, the Palucks referred to Karl as having a fever on January 21 and January 28. Their recitation of facts included:

Karl developed a fever of 101.5°F. on January 21, 2005. From January 21st through 28th, his day care providers noted Karl to be lethargic, irritable, tired, and to have a decreased appetite. They recorded a fever of 101.3°F on January 28, 2005. *There was no indication that Karl was ill prior to receiving his vaccines on the 19th or was otherwise ill during the January 21-28 time frame.*

Pet’r Posthr’g Br., filed Feb. 18, 2011, at 6 (citations omitted and emphasis added).

If the Palucks intended to contend that Karl had a fever on days other than January 21 and January 28, it was incumbent on them to offer persuasive evidence supporting this contention. See Walther v. Sec’y of Health & Human Servs., 485 F.3d 1146, 1150 (Fed. Cir. 2007) (“[I]t would be unusual to require a party to prove that ‘there is not a preponderance of evidence,’ as our legal system rarely requires a party to prove a negative.”). In absence of this showing, the undersigned

(. . . continued)

testified “He was lethargic. He was irritable. He was tired, had a decreased appetite, so he had systemic signs of being sick or of, as we had talked about, immune activation, these immune mediators actually being increased, and possibly this process already going on of this cascade of metabolic decompensation.” Tr. 103:23 to 104:3. To Dr. Frye, Karl’s irritability and lethargy was a manifestation of an encephalopathic process. Tr. 193:10-25. As part of cross-examination, Dr. Frye explained that the vaccines activated Karl’s immune system and the activated immune system produced a fever. Tr. 196:25 to 197:3.

Dr. Snodgrass agreed that Karl’s daycare reported a fever on two days. Dr. Snodgrass testified that the varicella and MMR vaccines, which contain live viruses, “do cause a fever in some children, but it takes time to appear. And it usually will not appear until the seventh or eighth day.” Tr. 338:23 to 339:1. Dr. Snodgrass disagreed with Dr. Frye’s causal connection of Karl’s January 2005 vaccinations and his subsequent fever. Dr. Snodgrass stated that “a fever two days after immunization is unlikely to be due to those immunizations.” Tr. 339:1-2.³⁰

Even though Karl had a fever on two days in January, Dr. Snodgrass stated that Karl was, overall, healthier than he was a few months earlier. Dr. Snodgrass stated “there is a contrast between November and December 2004 when there were many doctor visits and phone calls and January and February when there were not.” Tr. 336:19-22. In this same portion Dr. Snodgrass reiterated:

[W]e have this marked contrast between November and December when he was often seeing the doctors, either in Bismarck or at the Dickinson Clinic or his parents were telephoning them.

So I have every reason to believe that his parents are attentive to his needs, so I have to conclude that he was more sick in November and December than he was in January or February.

Tr. 341:22 to 342:5. More evidence of Karl’s relatively improved state of health is that the rash, which had been episodically recurring in Karl throughout the fall

finds that in the two weeks following vaccine, Karl had a fever only on those two dates.

³⁰ On cross-examination, Dr. Snodgrass elaborated about the basis for his opinion that fevers occurring shortly after an MMR or varicella vaccination are not caused by the vaccine. See Tr. 570:20 to 576:20.

2004, was better on January 19, 2005. Tr. 445:9-10.³¹ Karl also did not stay home from daycare. Exhibit 22 at 1-2; see also Tr. 565:21-22 (Dr. Snodgrass's testimony that one reason that he thinks the vaccinations did not significantly aggravate Karl's condition was the lack of evidence showing "significant regression, being sick, calling the doctors, staying home from day care, et cetera"). Concisely stated, Dr. Snodgrass's opinion is that "Karl was not seriously ill in January." Tr. 558:8.

On January 31, 2005, Karl's daycare provider reported that Karl was acting "very tired fussy." It also says "He has spots all over his arms & legs again." Exhibit 22 at 2. Dr. Snodgrass stated that "I think that [report of more spots] is more of the erythema multiforme. . . . And that could be associated with fever and irritability." Tr. 339:20-25. In the rebuttal phase of the hearing, Dr. Snodgrass testified that "the simplest explanation" for the January 31, 2005 incidence of red spots "is that the erythema multiforme waxes and wanes and that was a period when it was more evident." Tr. 804:9-11.³²

There are additional reports from the daycare provider for each day between February 1, 2005, and February 4, 2005, inclusive. For two days, Karl was reported as being "tired." On an intervening day, Karl "did very good today." Exhibit 22 at 2.

On February 7, 2005, the daycare notes state that Karl went to a chiropractor, and the details of this appointment are provided below. On February 8, 2005, the daycare record says: "Karl not very content not sleeping very long 1/2 [hour] at a time[,] tries to crawl pulling his body." Exhibit 22 at 2.³³

³¹ In the history of present illness section of Dr. McDonough's form, the note says "Recheck rash – better [with] Desonide." Dr. McDonough's assessment includes "recurrent erythema multiforme." Exhibit 5 at 62.

³² Dr. Frye also viewed the presence of red spots as an indication that Karl's erythema multiforme had recurred. Dr. Frye connected the erythema multiforme with an activation of Karl's immune system that was, in turn, caused by the vaccinations. Tr. 645:2-14.

³³ This is the final daily entry from the daycare record. See footnote 28, above.

2. Chiropractic Records

On February 7, 2005, Ms. Paluck brought Karl to his first appointment at the Pokorny Chiropractic Clinic.³⁴ The “present complaint” was that Karl was “Not crawling / walking.” On the intake form in the blank associated with the typed text “pain described,” there is handwriting saying that “ear infections – w/ red spots on extrem[ities].” Exhibit 12 at 1.³⁵ (This handwriting is probably the handwriting of a person from the chiropractic clinic.) Another part of the intake form has different handwriting, which is probably from Karl’s mother, saying that the reason for Karl’s visit was “infant – not crawling, walking, problems sitting – sometimes.” *Id.* at 2.

On another form, which the chiropractor used to record the treatment provided at each visit, there is a series of boxes adjacent to the letter “O,” which presumably stands for “objective.” The boxes are labeled Progress, NCM, Palp, MP, Antalgia, Spasm, Edema, Pain/Tender, ROM C/S, ROM L/S. Some boxes contain handwritten dashes, letters, or arrows, pointing either upward or downward. The significance of these entries is not clear. Neither Dr. Frye nor Dr. Snodgrass discussed these boxes in their testimony. Similarly, neither the Palucks nor the Secretary referred to these boxes in their recitation of Karl’s medical history in the briefs filed after the hearing.

³⁴ Although Dr. McDonough had referred Karl for physical therapy and occupational therapy following the January 19, 2005 appointment, the Palucks were not taking Karl for therapy. One of Dr. McDonough’s later records explains that the Palucks thought that Karl’s problem was a “pinched nerve which is interfering with his development.” Exhibit 3 at 7.

³⁵ When the Secretary’s counsel asked Dr. Snodgrass about whether this report of pain meant that Karl had otitis media, the Palucks’ attorney objected due to lack of foundation. Dr. Snodgrass agreed with the Palucks’ attorney, saying that chiropractors “would not try to decide whether a person has an ear infection or not.” Tr. 341:13-14.

On the other hand, Dr. Snodgrass testified—without any objection—that a chiropractor could report the presence of a rash accurately. Tr. 340:9, 341:7-8.

For Karl's first visit, the chiropractor's notes, which are difficult to decipher, has in the "comment section," the following:

Dr. [Steven] McDonough / Bismarck / MedCenter 1 Clinic
X Pt. tenderness sub occip (R) ↓ ROM / head / Pot

Exhibit 12 at 4. The chiropractor's assessment was "C-Seg. Dys." Id. at 5.³⁶

Two days later, Karl returned. He was described as "irritable." There is also a notation, perhaps preceded by an asterisk, saying "Pt hip [after] cross crawl." Id.³⁷ After two more days (February 11, 2005), he was described as "spastic." Id.

In his rebuttal testimony,³⁸ Dr. Frye saw "irritable" as a presentation that was "somewhat unlike Karl because he's been described as being a very happy child until the January 19th." Tr. 647:1-3. Dr. Frye then discussed why the report of spasticity was "interesting" to him. He saw "spasticity" as marking a significant change in Karl's status:

[A]s I mentioned before[,] changes in tone sometimes are very subtle things. Spasticity though suggests a very severe neurological event, . . . and [for] spasticity to actually develop within the time frame that we see, within a month, suggests that there was very rapid change in his central nervous system. So whereas tone is something that you feel as far as the resistance to passive flexion, spasticity actually suggests that there's actually significant damage where the muscles

³⁶ Neither party asked Dr. Frye or Dr. Snodgrass to interpret this note. It might mean that the chiropractor assessed Karl as having a dysfunction in the cervical segment of his spine.

³⁷ With reference to this visit, Dr. Frye said that the chiropractor "makes a note of some abnormalities of his of [sic] bilateral hips with cross crawl." Tr. 647:4-5.

³⁸ Dr. Frye did not mention Karl's visits to the chiropractor in his reports of March 30, 2009 (exhibit 16), July 17, 2009 (exhibit 21), or January 11, 2011 (exhibit 40). Dr. Frye also did not discuss the chiropractor's records in his testimony during the first day of hearing. See Tr. 32-242. Similarly, when the Palucks prepared a demonstrative exhibit presenting a "Time Line" for Karl, the Palucks did not include any entries from the chiropractor. See exhibit 24.

are being contracted forcefully because they have actually lost control from the brain.

Tr. 647:12-23. Dr. Frye stated that in his review of Karl's records prior to February 11, 2005, he did not discover any caregiver noting spasticity during an examination. In Dr. Frye's view,

this suggests that there is significant damage to the brain, what we call an upper motor neuron lesion, and that the neurons in the motor cortex are severely damaged and are no longer controlling the neurons in the spinal cord. And within that time period to go from maybe some increased tone to becoming spastic suggests a very quick and fast regression.

Tr. 648:7-14.

The next entry from the chiropractor is three days later, February 14, 2005. Karl is reported as being in a "better mood." Exhibit 12 at 5. Karl returned on February 16, 2005, and the chiropractor described Karl as "less rigid – more comfortable on all 4's." Id. On February 18, 2005, the notation is "less rigid – 'happier.'" Id.

The Palucks did not elicit any testimony from Dr. Frye about the February 14, February 16, or February 18, 2005 records. See Tr. 648:20 to 649:1 (Dr. Frye's testimony describing visits on February 11, 2005 and March 30, 2005); see also Tr. 649:20 to 650:6 (the Palucks' attorney drawing Dr. Frye's attention to a visit on March 17, 2005).

In his direct testimony, Dr. Snodgrass referred to the chiropractor's records as not showing a change in Karl.³⁹ He stated that the records from the Pokorny Chiropractic Clinic "talk about problems. In fact, they use the word spastic in various places[.] . . . They often say spastic, stiff, et cetera. So they are reporting on the same general phenomenon which first became evident to Dr. McDonough in January." Tr. 336:24 to 337:4.

³⁹ Dr. Snodgrass's expert reports also did not discuss Karl's experience at the chiropractor. See exhibits A, N, and BB.

Karl continued to go to the chiropractor every few days from February 20, 2005 to March 10, 2005, inclusive. The portion of the form labeled "S," which presumably stands for symptoms, contains different handwritten notations, of which some are difficult to read. Entries include "stiff," "irritable," "less fussy" in association with increased bowel movements, "less hypertonicity," and "irritable" in association with not sleeping well. Exhibit 12 at 6-7. Neither Dr. Frye nor Dr. Snodgrass commented on these particular records.

In the middle of this period, Ms. Paluck brought Karl to the pediatrician's office because Karl's mom thought he might have an "ear infection." In addition, Karl "has been a little bit fussy. Also has been coughing some and has had a bit of rhinorrhea for the past couple weeks." Karl was, at this time, "eating and drinking fair. Making urine." The doctor's objective examination of Karl included that his head, eyes, ears, nose and throat were "normocephalic and atraumatic." The doctor assessed Karl as having "Bronchitis with irritability. No current evidence of otitis media." Exhibit 3 at 63.

From this information, the doctor planned that Karl should receive "[s]ymptomatic cares [sic]." The doctor recommended maintaining the routine checkups with Karl's pediatrician. Id.⁴⁰

On March 17, 2005, Karl saw the chiropractor for the fourteenth time since February 7, 2005. For "S," the handwriting states "upper [illegible, perhaps "ext" for extremities] skin blotches – back pain." (This handwriting is not the same as the previous entries.) For "A," which presumably stands for "assessment," the record says "palpation of spine painfull [sic] Baby cries loud when touched." Dr. Frye commented that the report of back pain and loud crying when touched "is suggesting that [Karl's] starting to have spasticity of some of the axial musculature and back pain, which would again suggest that he has some abnormal control of those muscles." Tr. 650:1-4. In Dr. Frye's view, "this is something that is progressive because we know previously he was a very happy child without any pain." Tr. 650:4-6.

The sequence of visits to the Pokorny Chiropractic Clinic is interrupted by a development at Dr. McDonough's office.

⁴⁰ In his initial testimony, Dr. Frye described this visit but did not add any additional meaningful information. See Tr. 105:9-106:4.

3. Social Services' Involvement and Dr. McDonough's Referral to Dr. Kriengkrairut

On March 22, 2005, Ms. Paluck returned a call from Dr. McDonough. This led to a joint phone call among Dr. McDonough, Karl's mom, and Karl's dad. Dr. McDonough records the following information:

Some brief crawling
Not sitting on his own
Leans to one side
Babbling more
Rash – comes + goes
[Illegible] testing CT scan

Exhibit 5 at 72. Dr. McDonough's plan is to refer Karl to a neurologist.

The Palucks' attorney drew Dr. Frye's attention to this record. Their attorney stated:

Q: . . . That's the first indication that we have that the pediatrician is now concerned such to a level that Karl needs to see a neurologist.

A: That's true. And it looks like something about testing with a CT scan.

* * *

A: . . . [Dr. McDonough] believes that some medical testing needs to be done[.]

Tr. 107:4-13.⁴¹

On March 23, 2005, Brenda Erie from Stark County Social Services called Dr. McDonough. The message was "Please call ASAP. Emerg[e]nt." While the reason for the call is "emerg[e]nt," the details that prompted the call were not

⁴¹ Much later in Dr. Frye's testimony, he stated "[i]f you look through the record, . . . the pediatrician's record, . . . after the vaccine there is no mention of him making any babbling sounds." Tr. 702:9-12. Dr. Frye was not asked about the March 22, 2005 phone call.

provided. Dr. McDonough returned this call approximately two hours later. His note states “Discussed peds neuro evaluation.” Exhibit 5 at 73.

Dr. McDonough completed a “Consultation Request Summary” on March 24, 2005. Dr. McDonough stated, “I have been contacted by a chiropractor in Dickinson who is providing care for Karl. I also received contact by Stark County Social Services regarding Karl’s lack of participation in physical and occupational therapy.” Exhibit 3 at 7. (Dr. McDonough’s referral does not explain how the Stark County Social Services learned that Karl was not attending therapy, as Dr. McDonough had recommended.) Dr. McDonough said that he has “talked to the parents and recommended a CT scan and medical evaluation for congenital infection and inborn areas of metabolism.” Karl’s parents, however, were “reluctant to do any medical evaluation” due to their belief that Karl’s developmental problems were caused by a pinched nerve. Dr. McDonough requested that Dr. Siriwan Kriengkrairut, a neurologist, conduct an “evaluation and medical investigation[] into the etiology of his developmental delay and hypertonicity.” Id.

Karl returned to his regular chiropractor on March 27, 2005. For the symptoms, Karl is reported to have “Rigid lower extrem[ities]. . . . ‘Doing well ‘til yesterday.’” The assessment is “same” and also says ““took a few crawl steps.”” Exhibit 12 at 7.

Although the March 27, 2005 chiropractor’s treatment record does not explain precisely how Karl changed after “doing well” until March 26, 2005, some additional information may be found for a visit on March 28, 2005. On that day, Ms. Paluck brought Karl to his pediatrician’s office in Dickinson.⁴² Dr. Gary Peterson, not Dr. McDonough, saw Karl for this appointment.

Ms. Paluck reported that Karl had “four days of wheezy cough, runny nose for two weeks.” Ms. Paluck also informed Dr. Peterson that Karl had been “[f]ussy, not eating well,” although no duration was specifically noted. Karl was reported not to be having any ear pain, diarrhea, or nausea. Exhibit 3 at 64.

⁴² Ms. Paluck originally called the clinic in Bismarck, but a nurse directed Ms. Paluck to make an appointment at Dickinson. Exhibit 5 at 74.

Dr. Peterson examined Karl, focusing on Karl's breathing. There is no mention of developmental milestones, such as crawling, speaking, or walking. Dr. Peterson diagnosed Karl as having "1. Early bilateral otitis media. 2. Bronchiolitis, suspect RSV." Id. Dr. Peterson treated Karl with SVN (small volume nebulizer) and prescribed an SVN for use at home. He did not prescribe any antibiotics, noting that "Mother has preferred no antibiotics be written as yet since he has had the trouble with erythema multiforme in the past." Dr. Peterson's note states "Recheck tomorrow morning to ascertain improvement. See sooner for shortness of breath." Id.

There is no information in the record indicating that the Palucks brought Karl in for medical treatment in the immediate days following his March 28, 2005 appointment with Dr. Peterson. The next visit was with the Pokorny Chiropractic Clinic on April 2, 2005. See exhibit 24 (Pet'r Timeline) at 3; exhibit H (Resp't Summary of Medical Records) at 10.

However, before Karl returned to the chiropractor, the chiropractor memorialized a "Phone convers[ation]" with a person whose name is difficult to decipher but was affiliated with "SCSS."⁴³ The caller was inquiring about a possible adverse vaccine reaction to which the chiropractor responded "No." The chiropractor also discussed "CP, cerebellar tumor." The people also discussed "P.T. / O.T. in conjun[ction] [with] chiro[practic] care." Exhibit 12 at 7.

In connection with this report, Dr. Frye testified that the chiropractor "also discusses . . . a possible adverse reaction to the vaccine." Tr. 649:16-17. Dr. Frye, however, failed to note that the chiropractor's opinion was that Karl did not have an adverse reaction to the vaccine. See id.; see also exhibit 12 at 7.

Dr. Frye interpreted "CP" as meaning cerebral palsy. To Dr. Frye, the reference to cerebral palsy was significant because "those children with cerebral palsy do have spasticity, but for here this is pretty significant that he has cerebral palsy which probably affects, which affects the limbs and the motor system to a significant extent, he actually puts in here that maybe he has a cerebellar tumor, suggesting that he has some ataxia or some inability to control his movements very well." Tr. 649:4-11.

⁴³ Given the information in Dr. McDonough's request for a consultation, SCSS probably refers to "Stark County Social Services" and the caller was probably Brenda Erie. See exhibit 5 at 73.

Dr. Frye continued his interpretation of the chiropractor's memorialization of a phone conversation. Dr. Frye stated that "this is more of what we would think of as a fine motor problem than a gross motor problem. So it seemed like he was suggesting that there was actually something more and progressive." Tr. 649:12-15. Unfortunately, Dr. Frye did not define what symptom evidenced a fine motor problem. Dr. Snodgrass did not respond to Dr. Frye's interpretation of the chiropractor's March 30, 2005 phone call.

On March 30, 2005, Ms. Erie from Stark County Social Services left another message with Dr. McDonough. Dr. McDonough's notes from the ensuing conversation recorded that "Mom told Pt that Baby is lazy + will await appt. Told her that appt has been scheduled in April with Dr. Siriwan." Exhibit 5 at 75.

Karl next saw the chiropractor on April 2, 2005. The chiropractor records the following: "Nebulizer this [illegible, perhaps week]. Up on all 4's longer – seeing improvement. Less rigid – 'good mood this week' – taking a few crawling steps." On the line for assessment, the chiropractor has written in parenthesis "No red spots for 2 wks." On the same line, the chiropractor has also written "*'Doing well OT/PT since Nov.' '1-2x/wk.'"⁴⁴ Exhibit 12 at 7. The chiropractor's use of quotation marks suggests that Ms. Paluck provided the information about Karl's history of occupational therapy and physical therapy. However, the Palucks have not submitted any records documenting Karl's participation in occupational therapy or physical therapy.

Ms. Paluck brought Karl back to the Dickinson pediatric clinic on April 4, 2005, where they again saw Dr. Peterson. The reason for the visit was Karl's ears were draining. The doctor's examination focused again on respiration. The doctor mentioned that Karl was not having a rash. Dr. Peterson diagnosed Karl as having "Bilateral otitis media, draining on the right." He also said that Karl's bronchiolitis was improving. Exhibit 3 at 66.

Dr. Peterson recommended weaning Karl from the nebulizer, and prescribed Augmentin. Dr. Peterson also instructed Ms. Paluck to watch for rashes, hives, or erythema multiforme. Id.

⁴⁴ As noted in the text, these words appear on the line for assessment. However, they may appear there only because there was no more room on the line for "symptoms."

On April 8, 2005, Karl saw the chiropractor again. The chiropractor reported Karl's "cold symptoms better." There is an "X" inside a circle followed by "Antibiotic / 1 wk. Augmentin." There is another circled X followed by "Discussed file with parents. 'You make decisions re: Karl's care.' 'Not concerned.'" Exhibit 12 at 7.

On April 11, 2005, Mr. Paluck telephoned Dr. McDonough's office. Mr. Paluck reported that "Karl is crawling about 2 wks ago." Mr. Paluck also wanted Karl's "ears checked." The nurse advised Mr. Paluck "to keep appt they have scheduled." Mr. Paluck agreed. Exhibit 5 at 76.

The Secretary's counsel discussed this notation with Dr. Snodgrass. The discussion was as follows:

Q: And is it significant against your opinion of vaccine causation that Karl was crawling about two weeks ago as of April 2005?

A: It supports my view that Karl's problems were fluctuating. He had times when his symptoms were worse, he had times when he was improving. And on April 11th he was apparently doing better.

Tr. 794:10-16.

Due to Dr. Snodgrass's reliance on Mr. Paluck's statement that his son was crawling, the undersigned asked Dr. Frye his views:

Q: So here there's a telephone conversation record, Mr. Paluck is calling and he says that Karl is crawling about two weeks ago. How does Karl's crawling fit within your theory of the case?

A: I think that, you know, he has – well, you know, sometimes kiddos that have increased tone may find it easier to crawl because if you have normal tone you actually have to push off with your muscles. If you have actually stiff legs sometimes it's sometimes easier to actually crawl. So I don't know that it necessarily negates the fact that he had these neurologic abnormalities. And to tell you the truth this is about the same time that we know that he had spasticity. So I would say that he's actually just trying to learn to crawl despite his spasticity.

Q: Would crawling be evidence of a new achievement I guess?

A: I think it's hard to say because we know that neurologically he's so abnormal at this point, I don't know that we could really interpret it within the same context of normal development.

Tr. 826:18 to 827:15.

4. Dr. McDonough – April 13, 2005

The appointment to which the nurse referred took place two days later, on April 13, 2005. It was with Dr. McDonough. The purpose was to evaluate Karl before he received anesthesia as part of an MRI.⁴⁵ Because Dr. Frye and Dr. Snodgrass discuss this report extensively, much of Dr. McDonough's report is set forth below.

Dr. McDonough's report begins with a history of Karl's present illness. Dr. McDonough's summary is consistent with the preceding recitation of facts, although Dr. McDonough does not have details about Karl's status as recorded by the chiropractor. Dr. McDonough states:

Karl is a 14-month-old with global developmental delay who comes back in for a recheck. I have had numerous phone conversations with parents and have been trying to arrange evaluation for the global developmental delay and erythema multiforme. The parents have been reluctant to do this and are hesitant about any radiation exposure. They have not been taking him in to PT as requested but have been utilizing chiropractic services.

The parents have agreed to have him seen by Dr. Siriwan Kriengkrairut and I have also had several conversations with the Badlands Human Services regarding questions that they have had regarding his evaluation.

Exhibit 3 at 9. The next pertinent portion of Dr. McDonough's report is his review of systems. Again, this historical overview is consistent. Dr. McDonough writes:

⁴⁵ This MRI was probably scheduled in conjunction with Dr. McDonough's discussions with Karl's parents at the end of March 2005. The message from one call refers to the need for a consultation with a neurologist and a CT scan. Exhibit 5 at 72.

Positive for wheezing episode in March with otitis media. He has had chronic erythema muliforme but he has not had any lesions in the past three weeks. He has had global developmental delay and he has had increased irritability since he has been sick frequently this winter with ear infections. Previously, he was a very happy, laid-back child.

Id.

Dr. McDonough next describes Karl's developmental history. Dr. McDonough states: "Reveals that he does not sit yet. He moves a little bit more on four-point. He is not being followed by PT or OT as requested, but is seeing a chiropractor." Id.

Dr. McDonough then reports about his examination of various aspects of Karl. Pertinent parts include:

GENERAL: Karl is a vigorous, active 14-month-old with global developmental delay. He cries when he lays on his back but is smiley and happy and playing when he is sitting on his mom's lap.

HIPS: His hips are tight with decreased hip flexion to about 70 degrees bilaterally with increased [sic, a word is probably missing] in the lower extremities. This is a change on hip movement over the last couple of months. I did call Dr. Siriwan Kriengkrairut. Did encourage x-rays to be done of his hips but mom is reluctant to have this done.

* * *

SKIN: He has a bruise on his upper forehead and a couple of tiny bruises in his lower back. The bruise is from falling forward and hitting his head, according to mom.

NEUROLOGIC: Examination reveals increased [sic, a word, perhaps "tone," is probably missing]⁴⁶ in the upper and lower extremities. Deep tendon reflexes are present. I do not sense any clonus. Pupils equal, round, and reactive to light.

Exhibit 3 at 10. Based upon this information, Dr. McDonough assessed Karl as having "Global developmental delay with resolving otitis media."

⁴⁶ The Palucks' attorney suggested that the missing word was "tone." Tr. 108:23-25.

Setting aside concerns about an ear infection, Dr. McDonough set forth the following plan:

The plan is to follow up with Dr. Siriwan Kriengkrairut next week. Dad did call and agree to an MRI and an MRI has been ordered on 4/26/2005 at 7:00 a.m. Hopefully, the parents will agree to evaluation for congenital infections, metabolic disorders, and other tests requested by Dr. Siriwan for his global developmental delay. He is not speaking at this point and has obvious speech and fine and gross motor developmental problems with some apparent hypertonicity.

Id.

As alluded to earlier in this decision, Dr. Frye and Dr. Snodgrass testified about Dr. McDonough's April 13, 2005 report extensively, much more than either doctor testified about the chiropractor's records. In his initial testimony, Dr. Frye stated that Karl has deteriorated. Dr. Frye testified:

A: So now his [Dr. McDonough's] examination has significantly changed, because now he has increased tone in the upper and lower extremities, so – and he says, 'Global developmental delay with resolving otitis media.' So here his concerns are that his neurological exam has gotten worse.

Q: And that's worse from the examination that had been done, both in January of 2005 and December of 2004.

A: Yes. Exactly.

Tr. 108:15-22.

When Dr. Snodgrass testified, he disagreed with Dr. Frye's view that Karl had gotten worse. In reference to the passage just quoted, Dr. Snodgrass said: "I think he's missed the point that Karl was abnormal in the fall and by January he was showing new findings of increased tone. And that that was an important marker, something significant had changed." Tr. 338:5-9.

In the rebuttal phase, Dr. Frye responded to Dr. Snodgrass's opinion. The discussion between the Palucks' attorney and Dr. Frye in reference to Dr. McDonough's April 13, 2005 examination was:

Q: And would that be important for us in understanding what he finds in April versus what he found in January?

A: Well [in] January again he had this isolated gross motor delay and maybe a little bit of increased tone. Here he is described as having global developmental delay. And again if you have delays in just one area you have an isolated delay and it's not called global developmental delay. Global developmental delay is when you're affected in several areas. And so now he's describing a very different child who has global developmental delay, that is he has now delays in many different areas. And, you know, of course it probably isn't as accurate as what he should have said would be regression in certain areas, because he previously was not delayed in these other areas.

Q: Would you take us through the physical examination that Dr. McDonough made on April 13th, 2005?

A: Sure. Also I wanted to mention that he has a very interesting statement here as he's talking about Karl as having increased irritability since throughout the winter. And of course as we had seen in previous exams Karl was not an irritable child, he was a very happy child. Then when we actually look at the exam it says that he has decreased hip flexion, something he had not mentioned [sic] previously, and that hip flexion is decreased suggesting that again he has spasticity, not just increased tone but spasticity, limitations in his range of motion, which is what the chiropractor had mentioned back in I believe it was February, February 11th. So this is very different than, you know, just a difference in tone. And now he's seeing this because this is the first time he's seen Karl since the previous examination.

Q: And the examination that Dr. McDonough is doing on the 13th is a pre-MRI examination, is it not?

A: It is, yes it is.

Q: And so what else did Dr. McDonough find on April 13th?

A: So he also showed, let me just look at this. So it's interesting he's seeing bruises because now Karl is falling and hitting his head, so it suggests that he's lost actually coordination.

Q: The neurological exam?

A: He has increased tone in his upper, now his upper and his lower extremities. And he also mentions that he is not speaking at this point. So on the 19th he was actually saying mama and dada, but now he's not speaking at all. And he has obvious speech, fine, and gross motor developmental problems. So before, where the Denver had

actually showed us that he was normal in fine motor and language, now we're seeing that he has multiple developmental problems and he has lost all of his speech.

Q: Would these findings on April 13th, 2005, suggest regression in Karl's development?

A: Most definitely.

Tr. 651:9 to 653:18.⁴⁷

In one portion of this passage (Tr. 652:12-14), Dr. Frye states that Dr. McDonough's report of "decreased hip flexion" means that Karl had spasticity. Dr. Frye explained that "decreased hip flexion" is "just another term for spasticity." He continued:

So that means there's a limited range of motion. So spasticity causes a limited range of motion. So he is also, he's talking about the exact area where there's limited range of motion because of the spasticity.

⁴⁷ In this passage, Dr. Frye made several assertions that are not entirely accurate. For example, he testified that in January, Karl had "maybe a little bit of increased tone." Tr. 651:13-14. However, in January, Dr. McDonough indicated that Karl's neuromuscular system was abnormal and Karl had increased muscle tone in his upper and lower extremities. Exhibit 3 at 3 (progress note), exhibit 5 at 35 (Denver screening form).

Next, Dr. Frye mentioned Karl's irritability. Tr. 652:6. But, the full context of Dr. McDonough's report is that Karl has "had increased irritability since he has been sick frequently this winter with ear infections." Exhibit 3 at 9. This irritability is consistent with Karl's pre-vaccination history in which he was reported to be fussy in the context illnesses. See id. at 52, 58, 60. Dr. McDonough also reported that Karl is "smiley and happy and playing when sitting on his Mom's lap." Id. at 10.

In addition, Dr. Frye testified that on January 19, 2005, Karl "was actually saying mama and dada." Tr. 653:9. Actually, Karl's ability to say words on January 19, 2005 was more ambiguous. Although the Denver screening form contains a "pass" for "dada-mama specific," exhibit 5 at 35, Dr. McDonough's own form does not include a positive notation for this skill. See exhibit 3 at 3. In any event, even if Karl could say "mama" and "dada" on January 19, 2005, this limited ability is still a decline in his language abilities from December 27, 2004, when Karl "ha[d] several words that he says." Exhibit 3 at 5.

You see he says the hips are tight, so tight is another word for spasticity, meaning the muscles are so tight they're bringing the hips, they're limiting the hips' ability to move in their normal range.

Tr. 727:23 to 728:7; contra, Tr. 824:22 to 825:8 (Dr. Frye stating that he does not think that Karl had spasticity on January 19, 2005).

After hearing Dr. Frye's testimony, Dr. Snodgrass was asked to explain whether the vaccines changed the course of Karl's disorder. Dr. Snodgrass stated that he saw "no evidence that the vaccines changed the course of [Karl's] disorder." Tr. 793:5-6. Dr. Snodgrass stated (again) that he thought that Karl's clinical course fluctuated before and after the vaccine. In this context, Dr. Snodgrass stated, "I think the amount of hip flexor abnormality that was present was probably greater in April than in January, but there was no ankle clonus. So in other words we have certain areas where he looked a bit worse than he did in January and others where he did not." Tr. 793:14-19. Dr. Snodgrass also discusses here Karl's visit to the neurologist, Dr. Kriengkrairut.

5. Dr. Kriengkrairut on April 19, 2005

Dr. Kriengkrairut saw Karl on April 19, 2005 because Dr. McDonough had referred Karl "due to delayed development, not sitting up yet, unable to keep balance when he is sitting up." Exhibit 3 at 83. Like Dr. McDonough's April 13, 2005 report, Dr. Kriengkrairut's report is quoted here in detail because the experts rely upon this report so heavily.

Dr. Kriengkrairut's recitation of Karl's history begins with his birth. In pertinent part, Dr. Kriengkrairut recounts the following information beginning with the onset of the erythema multiforme:

Mother felt that he did well in the first 6 months, then he did have some problem with serious skin lesion. This was approximately in October 2004. According to the father, his whole body swelled up. . . It was diagnosed as erythema multiforme, suspected secondary to medication hypersensitivity reaction, exact allergy was unknown. This was also secondary to viral infection. According to the father since then, the child has regressed.

Exhibit 3 at 83. The parents' narrative (as written by Dr. Kriengkrairut) explains what happened to Karl before he was vaccinated:

In December of 2004, his condition got worse. His hands and feet were swelled up. He was given medications.

Id. At this point, it appears that Dr. Kriengkrairut is presenting information about more recent history.

This [sic, a missing phrase might be “skin condition”] has markedly improved from a month ago when he seemed to be back to normal. Father reported that since he has been improving with the skin lesion, he also has made progress in terms of development, but overall he is still behind. Parents reported that he has tendency to do fisting of both hands, even when he holds a bottle he will keep his hand clenched up. Recently, he seemed to open his left hand more.

Id. Then, Dr. Kriengkrairut describes various attempted interventions.

Mother has tried chiropractic treatment in him. She was told that the child had some stiffening of the extremities secondary to a nerve pinch in his back. Dr. McDonough has ordered physical and occupational therapy in Dickinson; however, parents have not made the appointment yet. Parents are very reluctant for any therapy treatment. Mother felt that the child is unable to sit up due to unable [sic] to balance secondary to curvature of his back. Recently he was able to crawl 2-3 crawling movements at the time.

He has not made any specific words. He has been sick quite often. This includes frequent ear infections.

Id.

Dr. Kriengkrairut’s review of systems is relatively brief, repeating some of what was just stated. For skin, Dr. Kriengkrairut reports Karl’s past history of erythema multiforme and says that “[i]n the last one month, seems to be doing much improved.” Exhibit 3 at 84. For neurologic, Dr. Kriengkrairut states “[t]he parents were told that he has stiffening of both legs and also delay.” Id.

As part of the physical examination, Dr. Kriengkrairut conducted a motor examination. This “revealed truncal hypotonia with marked spasticity of the extremities. The baby has tendency to do cortical thumb bilaterally, worse on the right compared to the left.” Id.

Dr. Kriengkrairut also used the Denver screening test. Dr. Kriengkrairut recorded: “The patient unable to sit alone, does have good eye contact, able to follow in all directions. The baby does not babble. Parachute reflex is not detected.” Id.

Dr. Kriengkrairut reached three impressions about Karl: “1. Global delayed development. 2. Truncal hypotonia with hypotonicity of the extremities. 3. Etiology to be determined.” Id. She also recommended various things to the Palucks, including that Karl would benefit from physical and occupational therapy.

Since Dr. Kriengkrairut’s evaluation was the first time Karl saw a neurologist, Dr. Frye and Dr. Snodgrass discussed her assessment extensively. In Dr. Frye’s direct testimony, he mentioned the following problems that Dr. Kriengkrairut reported as significant: Karl’s irritability, fisting, truncal hypotonia,⁴⁸ spasticity in his extremities, and bilateral cortical thumbing.⁴⁹ Tr. 110:2 to 112:9. Karl’s lack of babbling, as reported by Dr. Kriengkrairut, was especially important to Dr. Frye because Karl was babbling before his January vaccinations. See exhibit 3 at 3. The decrease in babbling is “suggesting that now he’s losing cognition and language . . . It’s suggestive of neurodegeneration or regression in development, which is caused by mitochondrial disorder.” Tr. 112:24 to 113:7.

Dr. Snodgrass disagreed, at least in part. Dr. Snodgrass viewed other abilities, such as Karl’s ability to roll over, as consistent between Dr. McDonough’s January 19, 2005 evaluation and Dr. Kriengkrairut’s April 19, 2005 assessment. See Tr. 358:13-25. For Dr. Snodgrass, “Dr. Siriwan is not finding that Karl has lost a skill which Dr. McDonough had previously recorded as present.” Tr. 359:4-6.

On the other hand, when Dr. Snodgrass was asked to comment upon Dr. Frye’s testimony that Karl worsened between January 2005 and July 2005, Dr. Snodgrass stated Karl “got worse in April/May.” Tr. 367:16-17. Unfortunately,

⁴⁸ In truncal hypotonia, “the axial musculature cannot support [the person] to actually sit up in any way or probably even stand.” Tr. 654:14-16 (Dr. Frye).

⁴⁹ Cortical thumbing occurs when the thumb is inside a closed hand. It is normal in newborn children but abnormal by age one. Tr. 582:25 to 583:14 (Dr. Snodgrass), 705:1-9 (Dr. Frye).

Dr. Snodgrass was not asked to identify the features in Karl that made him conclude that Karl was worse in April or May than in January.

Near the end of the Palucks' cross-examination of Dr. Snodgrass, their attorney asked him about two of the features identified by Dr. Kriengkrairut that Dr. Frye saw as "new" findings. First, there was a question about cortical thumbing that Dr. McDonough had not reported in January 2005. Dr. Snodgrass stated, "I would not expect a pediatrician to notice that and that is a very minor finding. It was not reported by Dr. McDonough, it was not reported by the chiropractor. But I wouldn't expect either one of them to notice that." Tr. 577:21-25. Counsel then challenged Dr. Snodgrass: "[A]ctually cortical thumbing is quite a significant finding, isn't it?" Dr. Snodgrass replied "I would disagree with you." Tr. 578:1-3.

The second topic was the truncal hypotonia. Again, Dr. Snodgrass did not agree with the characterization that this problem was new in April. The exchange between the Palucks' attorney and Dr. Snodgrass was:

Q: Dr. S also made an objective finding in April 2005 of truncal hypotonia, that was not present in January 2005 either, was it?

A: It was not reported by Dr. McDonough.

Q: So that's a new finding.

A: I don't think so. In order to determine truncal hypotonia, you have to do things with the child which I don't believe a pediatrician would do. I think the issue about - -

Q: You don't know that for a fact though, do you, Dr. Snodgrass?

A: I don't know it for a fact as concerning Dr. McDonough. I deal with pediatricians and pediatric residents every day and I know what they do.

Tr. 578:4-17.

The undersigned asked Dr. Snodgrass to elaborate on his answers regarding truncal hypotonia and cortical thumbing. For cortical thumbing, Dr. Snodgrass stated "[i]n the context of multiple findings of increased tone in upper and lower extremities, the presence or absence of this finding is not significant." Tr. 583:19-22.

This dispute carried over into the rebuttal phase of the case. Dr. Frye said cortical thumbing “is a significant sign of advanced upper motor neuron lesions and something you don’t see with just some type of change in tone or even mild spasticity, that is a very significant finding.” Tr. 654:22-25. The presence of cortical thumbing means that the spasticity “now has affected the upper extremities too and actually the thumbs.” Tr. 655:9-10.

Dr. Frye also discussed the truncal hypotonia that Dr. Kriengkrairut detected. Dr. Frye stated that truncal hypotonia meant that Karl was not sitting. This is a significant change from January 2005, when Dr. McDonough reported that Karl could pull to stand. Tr. 654:11-25; see also exhibit 5 at 62 (Dr. McDonough’s report).

Dr. Frye also repeated the point that between January 2005 and April 2005, Karl lost language. Dr. Frye stated in January, Karl was saying “mama and dada,” which is more complex than babbling. Tr. 656:3-10; see also exhibit 5 at 62 (Dr. McDonough’s report). In contrast, in April, Dr. Kriengkrairut states that Karl was not babbling. Exhibit 3 at 84. Dr. Frye concludes that Karl “has an obvious very severe regression in language from where he was at 12 months.” Tr. 656:12-13.

When Dr. Snodgrass returned to testify again, he did not further address the cortical thumbing or the truncal hypotonia. Dr. Snodgrass did, however, comment upon changes in Karl’s language. Dr. Snodgrass pointed out that on March 22, 2005, Karl was reported to be ““babbling more.”” Tr. 789 (quoting exhibit 5 at 72).

6. April 27, 2005 MRI

Following Karl’s appointment with Dr. Kriengkrairut, he saw the chiropractor again. For symptoms, the chiropractor has recorded, among other things, that Karl had a decreased range of motion. Exhibit 12 at 8. Neither Dr. Frye nor Dr. Snodgrass commented upon this particular record.

On April 26, 2005, Karl entered Medcenter One Hospital for his scheduled MRI. Upon admission, Karl was examined by Dr. McDonough. The report from Dr. McDonough’s examination presents Karl’s history, which is consistent with what has been described previously. In terms of developmental history, Dr. McDonough states that Karl “rolls over but does not sit without support. He does not crawl and does not say any words.” Exhibit 3 at 12-13. For Karl’s skin, he did not have a rash. For Karl’s extremities, there were “no signs of ankle clonus.” For Karl’s hips, Dr. McDonough stated, “Hips are tight on range of motion of hips. I

have asked mom to have Dr. Siriwan Kriengkrairut evaluate his hips, as well, to see if we should obtain x-rays. Parents are very hesitant to do any irradiation of Karl.” Id. at 13. Dr. McDonough recommended that Karl have the MRI as ordered by Dr. Kriengkrairut and receive services to improve his development. Id.

When the Palucks were meeting with the anesthesiologist before the MRI, the Palucks told that doctor that they were concerned that Karl had a possible ear infection. The doctor requested that Dr. McDonough see Karl again. Exhibit 5 at 52.

Dr. McDonough’s notes contain a review of Karl’s systems. For this entry, Dr. McDonough wrote that Karl had a “runny nose, cough, fussiness, irritability, and possible otalgia.” Dr. McDonough also wrote “[w]e have been urging an evaluation for developmental delay and the parents have been somewhat reluctant to have this done and have agreed to have an MRI without contrast.” Exhibit 5 at 52.

Under “PLAN,” Dr. McDonough recorded his answer to Mr. Paluck’s question about what was happening with Karl. Dr. McDonough said that he thought Karl “had problems with development resulting from problems with his brain function and that we could not determine the etiology of this. I told him I did not think it was a pinched nerve as told them by the chiropractor.” As to a recommendation, Dr. McDonough stated that he “also re-encouraged them to get him in PT/OT. I had made this recommendation four months ago and it has yet to be accomplished. The parents decided to take him to chiropractor instead.” Dr. McDonough concluded the entry by stating that Karl was “somewhat croupy afterwards but seemed to be doing well when anesthesia sent him home.” Exhibit 5 at 53.

Karl did have an MRI as planned. The results included multiple images, including diffusion-weighted images. The doctor who interpreted the results stated: “The corpus callosum is intact. White matter distribution appears normal and myelination is appropriate for age.” The ultimate conclusion in April 2005, was that it was a “Normal MRI brain scan.” Exhibit 4 at 11.⁵⁰

⁵⁰ When Karl was hospitalized due to more serious neurologic problems in July 2005, this MRI was re-reviewed. Then, the MRI was interpreted as showing apparent abnormality in his corpus callosum. Exhibit 18 at 11.

(. . . continued)

The day after the MRI, Karl was seen at the Dickinson Clinic by Dr. Peterson. The chief complaint was that Karl had a croupy cough. Dr. Peterson records the history, provided by Ms. Paluck, that Karl had an MRI yesterday and that he needed a breathing tube. Dr. Peterson also recorded the history that Karl had been having cold symptoms for a few days before the MRI. Karl's parents estimated his pain level was "8/10." Exhibit 3 at 67.

Dr. Peterson assessed Karl as having "Croup, viral versus irritation from the anesthesia procedure yesterday for the MRI." Dr. Peterson recommended continuing an antibiotic, which Dr. McDonough had prescribed, and SVN treatment. Dr. Peterson also supported the parents' plan to see an ENT about having tubes placed in Karl's ears. Exhibit 3 at 67-68.

7. Speech Therapy

In early May 2005, Karl began seeing Trisha Getz, a speech therapist. Several of his next medical appointments were with Ms. Getz.⁵¹

At the initial evaluation, Ms. Getz recorded that the Palucks said that Karl "had an MRI last week which has 'wiped him out' and they report a decrease in many skills since undergoing the anesthesia."⁵² The Palucks provided information about Karl's sucking, drinking, and swallowing skills. Ms. Paluck "reports

During the course of the litigation, Dr. Snodgrass reviewed the original MRI scan. He, too, concluded the April MRI was abnormal. Tr. 371:11-13, 373:13-19; see also Tr. 484:16-20.

When asked whether he had reviewed the original MRIs, Dr. Frye stated that "I believe I did, although I haven't done that recently." Tr. 731:10-11.

⁵¹ Ms. Getz's reports tend to be written in all capital letters. When there is a quotation from Ms. Getz, it is restated using lowercase letters as appropriate without any notation of this alteration.

⁵² In addition to this account provided approximately seven days after the MRI, Ms. Paluck provided histories to other doctors in which she states that after the MRI, Karl lost abilities. See, e.g. exhibit 11 at 5 ("Mom states that since the MRI there has been a loss in abilities").

decrease in speech production in the last few months. Karl was able to produce a variety of consonants but consonant production has stopped and during today's evaluation only a couple vowel sounds were heard." Exhibit 6 at 5.

When Ms. Getz tested Karl, he scored in the first and third percentile for expressive language and auditory comprehension, respectively. In Ms. Getz's evaluation, she did not hear any "true words, vocal imitation, solitary vocal play or sound combinations." She did not observe Karl demonstrating comprehension of spoken phrases such as "let's go bye bye," although Ms. Paluck reported that Karl could understand those phrases at home. Ms. Getz recommended more speech therapy to improve Karl's expressive and receptive skills. Exhibit 6 at 5-6.

Dr. Frye stated that a comparison between Karl's language ability in October 2004 (the K.I.D.S. evaluation including the Bayley and Vineland) and Karl's language ability as measured in May 2005 "document[] that he's now lost language milestones considerably." Tr. 114:2-3; accord Tr. 657:24 to 659:6.⁵³ With reference to a slightly later speech evaluation, Dr. Snodgrass essentially agreed that Karl had lost language skills between October 2004 and May 2005. Tr. 471:5 to 472:8.

On May 9, 2005, Ms. Getz saw Karl again for 30 minutes of speech therapy. On four objective measurements (approximate sounds, combine sounds, produce consonants, and respond to commands), Karl scored a zero. Ms. Getz noted that Karl "cried throughout most of session. He appeared uncomfortable around new therapists and therapists today worked on building rapport with Karl." Ms. Getz recommended that rapport-building continue and that his parents let Karl see their faces when they are speaking. Exhibit 6 at 36.

Also, on May 9, 2005, Karl went to the chiropractor. This visit was his only visit in the month of May. There is very little information about this visit, no

⁵³ In discussing Karl's language abilities before the vaccination, Dr. Frye states that Karl "had no problems with language . . . at 12 months of age or before that." Tr. 658:5-7. Actually, Karl was slightly delayed in language. See exhibit 15 at 2-3.

However, Dr. Frye's arguably rosy characterization of Karl's ability in October 2004 does not change his overall point – that Karl's ability with language significantly deteriorated between October 2004 and May 2005. On this point, as noted in the text, the experts agreed.

arrows at all. For symptom, the entry states “not much strength since MRI.” Exhibit 12 at 8.

On May 11, 2005, Dr. McDonough wrote a letter about Karl to Dr. Kriengkrairut. It appears that Dr. McDonough did not evaluate Karl on this date. Rather, the letter summarizes results of various laboratory tests. The letter also states that the “MRI showed no abnormalities.” Dr. McDonough concludes, “At this point etiology of [Karl’s] developmental delay has not been discovered and may not be known.” Dr. McDonough requests Dr. Kriengkrairut’s opinion as to whether “a brain wave study would be of assistance as he does have intermittent irritability.” Exhibit 5 at 29.

Also, on May 11, 2005, Karl had an in-person consultation with Dr. W. Thomas Coombe, a specialist in ENT. Dr. McDonough had referred Karl because of recurrent otitis media. Dr. Coombe scheduled Karl for a “BTT” the next day. Exhibit 10 at 1-2. Karl did have tubes placed in both ears on May 12, 2005. Karl was given anesthesia. Id. at 5.

The same day, Karl had another speech therapy session with Ms. Getz. Ms. Getz recorded that she observed Karl swallowing from a bottle. Karl continued to score zero on the four objective measurements. Ms. Getz stated that Karl had “less fussiness throughout this therapy session.” He “did cry frequently but was able to be calmed easier through movement.” In addition, “Karl did reach for toys and reached for wanted items during play.” Ms. Getz also recorded that Karl “[c]ontinues to be seen by PT and OT for gross and fine motor concerns.” Exhibit 6 at 35.

The next session with Ms. Getz was on May 13, 2005. Based upon the previous session’s work, Ms. Getz introduced a new objective standard – “indicate desired toy by reaching for toy.” Karl did this task four times. He also “respond[ed] to commands” once. For two other objective tests (approximate sounds and produce consonant commands), Karl again scored zero. Ms. Getz’s assessment was that “Karl was calm and participated without excessive fussiness for the first 15 minutes of therapy and then became very fussy and cried the duration of the session.” Ms. Getz added that “Karl did appear to be able to sit better and communicate desire for toy with improvement from previous sessions.” Exhibit 6 at 34.

Karl saw Ms. Getz on May 17, 2005. As a subjective impression, Ms. Getz recorded that “Dad reports he believe’s [sic] Karl’s strength is increasing.” For

objective tests, Karl indicated a desired toy by reaching for it eight times. He did not approximate sounds. Ms. Getz's assessment was that "Karl was able to indicate his desired toy more frequently today than previous visits. Karl continues to cry during therapy although the amount of time crying is decreasing." She also stated that "Karl is producing much more eye contact with therapist and laughed while appearing to enjoy play with a ball. Karl would reach for the ball and the sign for 'more' was used consistently through therapy as was the sign for 'all done.'" Ms. Getz also recommended some stretching exercises to help reduce Karl's drooling, which Mr. Paluck associated with getting new teeth. Exhibit 6 at 33.

In the morning on May 19, 2005, Karl had another appointment with Ms. Getz. Under "subjective," Ms. Getz stated that "Karl appeared more tired today and mom reports he was given a decongestant which may have made him fatigued." Ms. Getz continued that "OT and PT noted his high tone was decreased today and mom reports they have really been working a lot with him at home. Karl appeared more relaxed today." In the "objective" section, Karl had a four for "reaching for desired toy." He still scored zero for "approximate sounds." Ms. Getz also introduced various stretching exercises for his lips and cheeks. Exhibit 6 at 32.

Also on May 19, 2005, Mr. Paluck brought Karl to the Dickinson Clinic where he saw Dr. Peterson. Mr. Paluck reported that Karl woke with green nasal mucus and was crying and unhappy. Dr. Peterson's record of "objective" measurements reports normal results, including "normal muscle tone" in Karl's musculoskeletal system. Dr. Peterson assessed Karl as having a "[s]inus infection and viral syndrome." Dr. Peterson recommended medications, including over-the-counter cold and cough medicine. Exhibit 3 at 69.

On May 20, 2005, Karl had another session of speech therapy with Ms. Getz. He reached for a desired toy six times but still could not approximate or produce consonants. Karl "tolerated stretches and vibration [to his mouth] with much less reluctance than last session." Exhibit 6 at 31. Karl performed similarly during a May 24, 2005 session. Id. at 30.

Speech therapy continued on May 26, 2005. His objective score for producing words or consonants was zero. Ms. Getz reported that "Karl still has not produced any vocalizations other than crying during therapy. Dad reporting hearing Karl say 'mom' at home in reference [to] his mom." Ms. Getz's plan for the next session was to "attempt tongue lateralization." Exhibit 6 at 27.

The next three sessions (May 27, 2005, May 31, 2005, and June 2, 2005) were relatively similar. In the first of these three appointments, Karl did not move his tongue to get a piece of cereal placed inside his cheek. In these sessions, Karl did not respond as well to the stretching exercises, possibly because his mouth was sensitive due to teething. Exhibit 6 at 24-26.

The June 2, 2005 treatment was Karl's 12th appointment. On this date, Ms. Getz created an "Outpatient Speech Therapy Recent Summary" for Dr. McDonough to review. Ms. Getz recorded that Karl's diagnosis was "global developmental delay," he had "good" motivation/cooperation, and his potential for rehabilitation was "good for stated goals." The treatment plan was for Karl to receive therapy three times per week for four weeks. Exhibit 6 at 23.

In the next speech appointment, on June 8, 2005, Karl could not reach a piece of cereal placed inside his cheek. Ms. Getz stretched Karl's mouth. During stretches, Karl cried and needed frequent calming. He reached for a desired toy four times. Exhibit 6 at 20.

On June 10, 2005, Karl returned to the chiropractic clinic for the first time since May 9, 2005. The notes for "symptoms" appear to read "Mid TT [illegible] Upper CP ↓." In the row of "objective" values, there is an upward pointing arrow for "progress" and a downward arrow for "ROM C/S." Exhibit 12 at 8.

On this date, Karl also had a visit for speech therapy. The progress note was relatively short, noting how many stretches were performed with Karl. Attempts for Karl to perform "tongue lateralization" were "not completed due to sensitivity in mouth with teething." Ms. Getz's assessment was "Karl's only verbalizations continue to be crying. He does appear to have increasing tone with oral motor structures. Continues to slowly progress." Exhibit 6 at 19.

Dr. Thomas Coombe, the doctor who placed tubes in Karl's ears, examined Karl as part of a follow-up appointment on June 13, 2005. One of the nurses recorded a statement from the Palucks that Karl "has had no ear infections and sleeps fairly well[]." Dr. Coombe reported that the tubes were in good position in the ears and expected the tubes would extrude in eight to nine months. Exhibit 10 at 21.

On June 14-15, 2005, Karl had speech therapy appointments with Ms. Getz. On both days, he appeared to be teething and his discomfort interfered with the

stretching exercises. Exhibit 6 at 18. On the latter day, Ms. Getz's assessment was "More attentive to new toys today. Pt smiling with play with cars while sitting on therapist[']s lap at table. Pt also enjoyed play with blocks. No vocalizations heard today other than crying." Id. at 17.

Karl had consecutive appointments at the Pokorny Chiropractic Clinic on June 16 and 19, 2005. On June 16, 2005, the chiropractor's handwritten notes for the subjective portion are particularly difficult to read. In the objective portion, within the "progress" box, there are two up arrows and one down arrow. In the "ROM C/S" box, there are two arrows, one up and one down. For June 19, 2005, there is a report that "Baby fell during storm last night." Another line states "Baby crying much more Relaxed Post [accident]."⁵⁴ Karl had a tender thoracic spine. There was a downward pointing arrow in the progress box. There was no entry for ROM/CS box. Exhibit 12 at 8.

On June 20, 2005, Karl returned for more speech therapy. Mr. Paluck reported that he had been trying to place food in Karl's cheeks as Ms. Getz had recommended, to encourage tongue lateralization. Karl tolerated stretches well. "Karl did appear to enjoy looking at books and models were provided for 'more' both verbal and signs. Animal sounds were also modeled for Karl to imitate including moo and baa." Exhibit 6 at 15.

Two more sessions were held on June 27 and 30, 2005. On both occasions, Karl was sensitive to stimulation in his mouth. Karl also was having difficulty protruding his tongue in both sessions. Exhibit 6 at 11-12.

On July 1, 2005, Karl went to the chiropractor. The information from this visit is sparse. The only word in the subjective line is "irritable." There are no arrows, either upwards or downwards, in any of the objective boxes. This was Karl's final visit to the chiropractor before the onset of seizures. Exhibit 12 at 8.

Karl's next three appointments were for speech therapy on July 5, 7 and 11, 2005. There is relatively little detail about Karl, mostly comments about how he responded to stretching exercises. Exhibit 6 at 8-10. The July 5, 2005 entry states

⁵⁴ This entry lacks a period. It is difficult to tell whether the chiropractor meant "Baby crying much more. Relaxed Post-[accident]." or "Baby crying. Much more relaxed Post-[accident]."

that Ms. Getz “attempted use of picture symbols with Karl looking at pictures but not reaching for or touching pictures.” Id. at 10.

Ms. Getz reported on her evaluation of Karl in a progress note she wrote to Dr. McDonough on July 6, 2005. She described Karl as “slow to progress toward goals, continues to work toward current goals.” She recommended that Karl be seen two times a week for four weeks. Exhibit 6 at 13.

8. Seizures and Hospitalization

On July 12, 2005, Karl was “napping and woke up and eyes rolled back into head and became unresponsive.” Exhibit 6 at 66 (report from ambulance service); accord exhibit 6 at 68 (report from emergency room doctor). An ambulance was called. When the ambulance personnel arrived, Karl responded to their voices with eye movements. Karl did not respond to physical stimuli. Later, Karl “returned unresponsive to verbal or physical stimuli.” The ambulance brought him to the local (Dickinson) emergency room. Exhibit 6 at 66.

At the emergency room, Karl’s mother, father and emergency medical service personnel provided a history. According to this history, Karl did not have a fever, ear pain, eye irritation or discharge, nasal discharge, congestion, sore throat, cough, or difficulty breathing. He also did not have vomiting, diarrhea, bloody stools, headache, difficulty with urination, joint pain, extremity pain or decreased urine output. The history of present illness includes a statement that Karl “is severely developmentally delayed.” His temperature was 100.5 initially and was 102.1 one hour later. Exhibit 6 at 68.

A doctor reviewed Karl’s systems and ordered laboratory tests. Karl also had a lumbar puncture. The doctor prescribed at least three doses of Ativan. The third dose came when Karl appeared to have another seizure while a doctor was examining him. After Karl remained in the emergency department for approximately six hours, he was transferred by ground ambulance to a hospital in Bismarck. Exhibit 6 at 68-69; see also id. at 62-65 (discharge summary from Dickinson).

Dr. McDonough admitted Karl to the Medcenter One Hospital in Bismarck. Dr. McDonough described Karl as a “17-month-old . . . with status epilepticus.” Karl “was in his normal state of health today when he developed his eye deviation, flaccidity, hypotonicity and jerking of his right arm.” Karl “later developed a fever.” Exhibit 5 at 55.

In Dr. McDonough's past medical history, he states that Karl has "global developmental delay." Karl "has seen Dr. Siriwan Kriengkrairut in evaluation." "He was to have urine organ [sic] acid, amino acids ordered and this was several months ago and has not been done so his initial evaluation as directed by Dr. Kriengkrairut has not been completed yet." Dr. McDonough also notes that Karl "is getting physical therapy and occupational services in Dickinson." Id.

For developmental history, Dr. McDonough wrote "he has no language. He does do some babbling." Karl "does roll over. He holds his head up well but has not been able to crawl, does not pull to stand." Id.

Dr. McDonough conducted a physical examination. He noted that "[m]uscle tone is mild increased tone lower extremities even with the medication effect. He has tight heel cords. There is no ankle clonus. Deep tendon reflexes are symmetrical." Exhibit 5 at 56.

Dr. McDonough's plan was to order more laboratory studies, an X-ray, and an EEG for the next day. He noted that Ms. Paluck was "anxious to get him down to the twin cities for neurological evaluation." Exhibit 5 at 57.

On July 13, 2005, Karl underwent an EEG. Dr. Kriengkrairut wrote the "neurodiagnostics report," interpreting the EEG as "abnormal." There was "generalized slowing of background rhythm, which may indicate cerebral dysfunction." Dr. Kriengkrairut recommended a follow up study noting the medications that Karl was taking could affect the results of the EEG. Exhibit 4 at 8-9.

Karl remained in Medcenter One Hospital for five days. Dr. McDonough presented pertinent information about his course, as well as the results of Dr. McDonough's examination when Karl was leaving the hospital in a discharge summary, dated July 16, 2005. Dr. McDonough assessed Karl as having "[g]lobal developmental delay with seizure disorder, possible deteriorating neurologic status in that he is unable to do some things that he was able to do previously." Dr. McDonough stated that there was "no obvious[] etiology on MRI," but when Dr. McDonough made this statement the abnormalities in the April 27, 2005 MRI had not been recognized. Dr. McDonough "suspect[ed] that he has an underlying seizure disorder which hopefully can be controlled with [medication]." Exhibit 3 at 18.

The plan was for Karl to go for more advanced evaluation at another hospital. Dr. McDonough arranged for Dr. Michael Frost at St. Paul Children's Hospital to see Karl and for unnamed doctors at Gillette's Children Hospital to see him as well. Id.

The first of these appointments took place on July 19, 2005, with Dr. Frost of Children's Hospital. As a prelude to the examination, an intern / medical student obtained a history of present illness.⁵⁵ In this account, Karl "began showing evidence of motor delay at appox[imately] 11 mo[nths] of age. He was trying to crawl and had some vocal sounds, was happy and using both hands purposefully."⁵⁶ The history continues: "He then developed rashes. He did have history of ear infections. His tone began increasing."⁵⁷ The history also states "By 14 mo[nths] no significant progress in development. He was seen by Dr. Kriengkrairut neurologist in April & MRI on 4/27/05 was read as normal." Karl's recent medical history continues: "Mom states that since the MRI there has been a loss in abilities[,] increase in tone with tremors with stimulation not present in sleep. He is extremely irritable." The intern / medical student also recorded that Karl "has [decreased] truncal tone with loss of some head control. He has been receiving therapies with some intermittent [decreased] tone but overall declining in all areas." Exhibit 11 at 5.

At this point, the history recounts Karl's immediate medical history, starting with the event on July 12, 2005. "[W]hile with baby sitter [Karl] woke up from nap[,] eyes rolled back & stiffened. Paramedics called. [Karl was] unresponsive on arrival & continued to seize." The history lists the medication and treatments Karl received while hospitalized. Id.

On the next page of the form, in the section for "past medical history," there is a notation "developmental 1st 6 mo[nths] of life." Also, "11 mo[nths] of age some evidence of motor delay... now loss of skills & seizures." Exhibit 11 at 6.

⁵⁵ The report mentions "By mom's report" and "Mom states."

⁵⁶ This portion of the history is supported by records created by Dr. McDonough. See exhibit 3 at 5-6 (report from December 27, 2004).

⁵⁷ The use of the word "then," suggesting that Karl developed rashes after he was 11 months old is slightly ambiguous. Karl had rashes before he was 11 months old and after he was 11 months old.

Dr. Michael Frost with assistance from a registered nurse, certified, saw Karl on July 19, 2005. Dr. Frost's report contains a lengthy history, noting that the information was obtained from Karl's mother, records from Medcenter One Hospital in Bismarck, and Dickinson Hospital. This history is particularly thorough and is consistent with the medical records created by Medcenter One Hospital and Dickinson Hospital. Dr. Frost's history states that Karl "was normal until approximately 6 months of age and then did have some mild delays." The history continues: "By 11 months of age, he had had multiple ear infections. He had also had [a] rash which was biopsied and diagnosed as erythema multiforme. He also had mild gross motor delay in that he was attempting to crawl but could not yet pull to stand." Exhibit 11 at 229. Dr. Frost's report mentions the referral to Early Developmental Services, the chiropractic care "for possible pinched nerve," the evaluation by Dr. Kriengkrairut, and the April 27, 2005 MRI. Dr. Frost details events beginning with the seizure on July 12, 2005. Id. at 229-30.

Dr. Frost stated that the question was "what etiology might be for his deteriorating neurological status and he is admitted at this time for further evaluation to determine etiology for his loss of skills." Dr. Frost's plan was to obtain "video EEG monitoring to clarify events and look at background, also to review previous MRI and look at what other diagnostic studies need to be undertaken." Exhibit 11 at 230. Dr. Frost intended to obtain an EEG, to repeat the MRI for comparison, and to consult specialists in hematology and genetics. Id. at 232.

After Karl was admitted, on the form for "patient orders," there is an entry for the "Nursing Patient History." This entry states that "Up until about [S]ept[ember] 2004 was meeting developmental milestones. Noted gradual but significant loss in motor skills, and speech. Declines gradually tapered and then in March/[A]pril of 2005 declines started again." Exhibit 11 at 225.

On July 20, 2005, a clinical geneticist saw Karl as Dr. Frost had requested. Dr. Mary Ella Pierpont obtained another history. Dr. Pierpont records that "[t]he family feels he was relatively normal for the first 6 months of life. By 9 months of life, they noticed that he was somewhat developmentally delayed. Prior to this, he was trying to crawl and some vocalizations. He used his hands in a purposeful manner. He held his head up well." Exhibit 11 at 234. Dr. Pierpont also examined Karl and recorded the results. Her assessment was that "[t]his young boy appears to have evidence of neurodegeneration. A particular diagnosis is not immediately apparent." Dr. Pierpont recommended another MRI. Id. at 235.

On that day, a pediatric hematologist, Dr. Christopher Moertel, also saw Karl for a possible iron deficiency as Dr. Frost had recommended. Dr. Moertel's history, which was taken from Karl's mother and father, begins: "Karl's past medical history is significant for his loss of milestones since approximately 11 months of age." Exhibit 11 at 46. The remainder of Dr. Moertel's evaluation is largely irrelevant because Dr. Moertel stated "I do not believe there is an association between the patient's iron status and the current neurological problem." *Id.* at 47.

On July 22, 2005, Karl had an MRI without contrast. The film from the April 27, 2005 MRI in Bismarck was available for comparison. The radiologist, Dr. Theodore J. Passe, found "[d]iffuse increased T2 signal throughout the cerebral white matter involving the deep and superficial portions of the white matter. . . . Moderate cerebral atrophy has developed since the last exam with further thinning of the corpus callosum." Dr. Passe's impression was that these findings "are consistent with a progressing leukodystrophy (consider hereditary, toxic or metabolic etiologies)." Exhibit 11 at 91.⁵⁸

Karl stayed in the epilepsy unit of Children's Hospital in St. Paul from July 19, 2005 to July 31, 2005. Additional details about his course for these 12 days are recorded in a narrative summary that Dr. Frost dictated after Karl was discharged. Dr. Frost states that the doctors looked at the April 27, 2005 MRI again. "In reviewing the previous MRI, it was felt that abnormality was apparent on that initial MRI, as well." Exhibit 11 at 52. During his hospitalization, the doctors placed a feeding tube in Karl. Dr. Frost's ultimate impression was that "MRI results are indicative of a neurodegenerative disease, felt to be likely progressing leukodystrophy. This was also confirmed by impression from geneticist. Further genetic testing to be pursued, depending upon findings from the lysosomal enzymes. Prognosis is guarded." *Id.* at 56.⁵⁹

⁵⁸ "Leukodystrophy" means "any of various types of neurodegeneration involving disturbance of the white matter of the brain." Dorland's Illustrated Medical Dictionary 1029 (32nd ed. 2012).

⁵⁹ The tests for lysosomal enzymes appear to present normal results. Exhibit 18 at 26.

9. Miscellaneous Visits, including Mitochondrial Testing

Three days after his discharge from Children's Hospital, Karl went to the Dickinson Clinic. His mother reported that he started having a runny nose five days previous and it had gotten worse. Dr. Oksa diagnosed him as having sinusitis for which she prescribed an antibiotic and noted his neurodegenerative disease for which he had been evaluated in Children's Hospital. Dr. Oksa requested that the Palucks bring in Karl again in about two weeks. Exhibit 3 at 70.

The follow up appointment with Dr. Oksa took place on August 15, 2005. Dr. Oksa deferred her examination, noting only "Fussy little boy being held by parent. No eye contact or purposeful activity." Dr. Oksa made some adjustments for Karl's nutrition, which he was receiving through a tube, and advised waiting for more information from laboratory studies that were still pending. Exhibit 3 at 72-73.

Although some records give information about Karl after August 2005, his development did not change.⁶⁰ On October 27, 2005, Karl had another MRI. This was Karl's third MRI, following other MRIs on April 27, 2005, and July 22, 2005. Dr. Frost's recitation of the results of the October 27, 2005 MRI was, in part:

Intracranial contents otherwise were not definitely changed from 07/25/05, again demonstrated some diffuse increased T2 signal in cerebral white matter with prominent thinning of the corpus callosum. This could represent nonspecific leukodystrophy. Alternatively, the progression of a signal change is [sic] between 4/27/05 and 07/22/05 may have represented evolution of 1 toxic/metabolic event, which is now stable.

Exhibit 11 at 280. In reference to the signal changes and stabilization in the corpus callosum, Dr. Frye explained that "the majority of changes in his brain occurred between the first two MRIs." Tr. 120:1-3.

As doctors continued to treat Karl, they looked to see if Karl could have a problem in his mitochondria. In October 2005, Dr. Frost at Children's Hospital in St. Paul arranged for a muscle biopsy. Exhibit 18 at 39. The results reflected a

⁶⁰ During the July 26, 2010 hearing, the Secretary commented that recent medical records had not been filed. Tr. 352:12 to 353:17.

“[p]robable [m]itochondriopathy.” *Id.* at 49-51. In August 2006, Baylor College of Medicine conducted more advanced tests and found more specific evidence of mitochondrial disorder. Exhibit 18 at 60.

As mentioned earlier in this decision, the parties have assumed that Karl was born with the disorder in his mitochondria. See Tr. 80:24 to 81:8 (Dr. Frye), 260:5-10 (Dr. Snodgrass), 377:7-11 (Dr. Snodgrass). Furthermore, the evidence preponderates in favor of a finding that Karl was experiencing neurological problems linked to his mitochondrial disease in October 2004, which is before he was vaccinated. See section III. above.

The question posed by this case is whether the Palucks have established that the January 2005 vaccinations significantly aggravated Karl’s mitochondrial disease. This question is answered by evaluating the six prongs of the Loving test. The first two prongs have been examined.

C. Loving Prong 3: Does Karl’s Current Condition Constitute a “Significant Aggravation” of His Condition Prior to the Vaccination?

The next portion of the Loving test is determining whether there is “significant aggravation” by comparing Karl’s condition before the vaccination to his current condition.⁶¹ The statute defines “significant aggravation” as “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration in health.” 42 U.S.C. § 300aa-33(4).

Here, Karl was much less healthy on July 30, 2005 (when he was discharged from Children’s Hospital) than he was on January 19, 2005 (when he received the vaccinations in Dr. McDonough’s office). By virtually any metric, Karl was worse.

⁶¹ As noted herein, the Palucks have not filed recent medical records. It is, therefore, somewhat of a misnomer to look at Karl’s “current condition,” strictly speaking.

D. Loving Prong 4: Is There a Medical Theory Causally Connecting Such a Significant Worsened Condition to the Vaccination?

The December 14, 2011 decision found that the Palucks had failed to meet their burden of proof on this issue. However, the Court vacated that finding, stating “it is plain that the special master required a higher level of proof from the Palucks than the Vaccine Act demands.” Opinion and Order, 104 Fed. Cl. at 473. The Court concluded its analysis of this prong by stating that the “Vaccine Act requires no more” than a “showing that [a theory] is sufficiently worthy and reliable to merit . . . extensive scientific inquiry.” Id. at 475.

In briefing after the Court’s Opinion and Order, the parties essentially agreed that the Palucks’ evidence met the standard as defined by the Court. The Palucks maintained that under the Court’s review of the entire record, “there is more than sufficient evidence to support a finding that Petitioners have met their burden of proof under all three prongs of Althen.” Pet’r Status Rep’t, filed May 7, 2012, at 7. The Secretary’s position was more equivocal, stating that “the Opinion may have hamstrung the special master from denying compensation under prong one of Althen.” Resp’t Resp., filed June 8, 2012, at 4. Although this statement is not an outright concession, the Secretary did not present any substantive argument regarding prong one of Althen in any of her post-remand briefs.

The finding that the Palucks have established prong one of Althen under the Court’s interpretation of what is sufficient evidence does not necessarily entitle them to compensation. Petitioners must still establish the second prong of Althen. See W.C. v. Sec’y of Health & Human Servs., 704 F.3d 1352, 1358 (Fed. Cir. 2013) (affirming special master’s denial of compensation for an alleged significant aggravation claim where petitioner failed to establish all three prongs of the Althen test); Hibbard v. Sec’y of Health & Human Servs., 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (finding no error in special master’s denial of compensation where petitioner failed to establish Althen prong two); Ricci v. Sec’y of Health & Human Servs., 101 Fed. Cl. 385, 391-92 (2011) (affirming special master’s denial of compensation where petitioners failed to show the existence of the prong two injury required by their prong one theory).

E. Loving Prong 5: Is there a Logical Sequence of Cause and Effect Showing that the Vaccination Significantly Aggravated Karl's Condition?

The December 14, 2011 decision found that the Palucks had failed to meet their burden of proof on this element. The decision was based upon two propositions. First, the Palucks' expert presented a theory in which the vaccine would cause a continual deterioration. 2011 WL 6949326, at *6-17. Second, that Karl did not decline in the manner that Dr. Frye predicted. *Id.* at *22.

The Court held that the December 14, 2011 decision was arbitrary and capricious with respect to the second finding. (The Court did not disturb the finding that Dr. Frye's theory was predicated on a downhill trajectory. See Opinion and Order, 104 Fed. Cl. at 476.) Without making any affirmative findings of its own, the Court vacated the December 14, 2011 decision for a discussion of the chiropractor's records, the treating doctors' "statements regarding the cause of Karl's decline," and Dr. McDonough's referral to a pediatric neurologist.

In accord with the Court's instructions, the three specific parts of the record will be discussed in more detail. Then, there is an overall finding.

1. Chiropractor's Records

Karl saw an unnamed chiropractor (or chiropractors) at the Pokorny Clinic, starting on February 7, 2005. Karl had nine visits in February, seven in March, four in April, one in May, and three in June. Karl had one appointment in July before his seizures started, and a single visit in 2006.

The two expert neurologists, Dr. Frye and Dr. Snodgrass, did not discuss the chiropractor's records extensively.⁶² Dr. Frye completed his direct testimony

⁶² In their posthearing brief, the Palucks summarized the chiropractor's records in one paragraph, containing seven sentences. Pet'r Posthr'g Br., filed Feb. 18, 2011, at 6-7. The Palucks also argued that the chiropractor's records support Dr. Frye's theory that Karl's neurological status changed dramatically. *Id.* at 19-20.

without citing the chiropractor's records once.⁶³ Similarly, when the Palucks presented a demonstrative "time line," summarizing the medical records, the Palucks omitted the chiropractor's records completely. See exhibit 23 at 8; see also exhibit 24 at 3.

When the Palucks called for rebuttal testimony from Dr. Frye, they elicited testimony from him about four specific entries from the chiropractor. Tr. 646:15 to 650:22. For February 9, 2005, the chiropractor described Karl as "irritable." Exhibit 12 at 5. Dr. Frye found this description significant because previously Karl was described as "a very happy child." Tr. 647:2-3. For February 11, 2005, the chiropractor described Karl as "spastic." Exhibit 12 at 5. Dr. Frye defined "spasticity" as "suggest[ing] a very severe neurological event." Tr. 647:14-15. Dr. Frye opined that spasticity "suggests that there was a very rapid change in his central nervous system," worse than the increased tone that had been found previously. Tr. 647:17-18.⁶⁴ On March 30, 2005, a chiropractor used the term "C.P." and mentioned a cerebellar tumor. Exhibit 12 at 7. Dr. Frye explained that children with cerebral palsy have spasticity and the reference to a cerebellar tumor "suggest[s] that [Karl] has some ataxia or some inability to control his movements very well." Tr. 649:10-11. Finally, the Palucks' attorney drew Dr. Frye's attention to the chiropractor's March 17, 2005 visit in which the chiropractor recorded that Karl "cries loud when touched" and mentioned back pain. Exhibit 12 at 7. Dr. Frye interpreted these notations as "suggesting that he's starting to have spasticity of some of the axial musculature and back pain, . . . and that this something that is progressive because we know previously he was a very happy child without pain." Tr. 650:1-3.

After reviewing these four entries, the Palucks asked Dr. Frye whether "any of the findings identified by the chiropractor in February and March of 2005" were

⁶³ The word "chiropractor" appears only twice in the transcript from the March 22, 2010 hearing. Tr. 7:6 (Respondent's counsel requesting any updated records from Karl's care providers, including his chiropractor), 31:3 (Petitioners' counsel's opening statement).

⁶⁴ Later, Dr. Frye stated that a "reactive spasticity" is "a sign of a problem with a lack of inhibition of certain muscles from the cerebral cortex consistent with a lesion, or that is not having the neurons in the cerebral cortex to inhibit certain motor neurons in the spinal cord." Tr. 705:22 to 706:1.

reflected in Dr. McDonough's January 19, 2005 examination. Dr. Frye responded that they were not; Karl was "a very different child." Tr. 650:11-12. To Dr. Frye, the chiropractor's notes show that "it's actually progressing as he sees the chiropractor." Tr. 650:13-14. After obtaining an opinion from Dr. Frye that Karl "had regression after the 19th [of January]," Tr. 650:20-21, the Palucks moved on to other topics and did not otherwise question Dr. Frye about the chiropractor's records.

However, the chiropractor created other records. These other records reflect observations made by a person in the health profession within two months of Karl's vaccination, and, as such the Court has directed a review of those records.

Records about which the Palucks did not elicit testimony from Dr. Frye are not entirely consistent with Dr. Frye's description of Karl as "a very different child." Tr. 650:11-12. While the chiropractor's second entry states that Karl is "irritable," and the next one says that Karl is "spastic," the next three entries say that Karl has a "better mood," is "less rigid – more comfortable on all 4's," and is "less rigid – 'happier.'" Exhibit 12 at 5 (entries for February 14, 16, and 18, 2005).⁶⁵ The last notation "'happier'" seems to contradict Dr. Frye's view that Karl was different when he was seeing the chiropractor because he formerly was "a very happy child," but after the vaccination was not.

The undersigned raised with Dr. Frye the notation that Karl was "less rigid." Dr. Frye stated that the physical therapy, which Karl was receiving through the chiropractor, would not correct a problem in the upper motor neurons. Tr. 726:19-20. However, manipulation of Karl's muscles "reset[s] the feedback mechanism that sets the tone of the muscle." Tr. 726:23-24; see also Tr. 812:15 to 813:12 (Dr. Snodgrass briefly explaining how damage to the spinal cord can cause hypotonicity).

This is the extent of Dr. Frye's testimony about the chiropractor's records. But, there are still more records.

On February 20, 2005, Karl was reported to be "stiff." He was also "Happy – moving around." In the box for progress, there are three arrows. The first two point up (suggesting improvement) and one arrow points down (suggesting

⁶⁵ For each of these three entries, there are upward pointing arrows in the boxes for "progress" and "ROM C/S."

decline). There is another down arrow for ROM C/S. The very next day, Karl is again “irritable.” For progress, there is one small arrow pointing up and next to it a dashed line. For ROM C/S, there is a single notation of an arrow pointing up. It is unclear whether these records mean that Karl is improving or worsening.

It is difficult to glean much significance from the chiropractor’s records, especially because the parties did not ask their experts to interpret them. The records are written in handwriting, which in places is difficult to decipher. The chiropractors have written their plans using abbreviations and codes whose meaning is not readily apparent. Neither party elicited testimony from Dr. Frye or Dr. Snodgrass to explain what phrases such as “T6, At (ASRA)” mean. Moreover, given that Dr. Frye and Dr. Snodgrass are medical doctors, not chiropractors, it is not even apparent that Dr. Frye or Dr. Snodgrass could assist.

Nevertheless, the chiropractor’s records have been studied. They contain some straightforward descriptions of Karl’s conditions. From February 9, 2005 through February 18, 2005 (inclusive), Karl is listed as “irritable,” “spastic,” “better mood,” “less rigid – more comfortable on all 4’s,” “less rigid – ‘happier’.” For this period of time, the “progress” box and the ROM/CS box contain a total of seven upward arrows and zero downward arrows. Exhibit 12 at 5.

On the next page of notes, there are six entries, covering from February 20, 2005 through March 8, 2005 (inclusive). Karl is described as “Stiff – mid TP – Happy – moving around,” “Mid T tite & SO P – irritable,” “spastic,” “No BM yesterday,” “BMs better – less fussy,” “Less hypertonicity, increased on all fours, BMs more regular.” In the “progress” and “ROM / CS” boxes, there are 12 arrows pointing upward.⁶⁶ Two arrows point down. Exhibit 12 at 6.

The next five entries are from March 10, 2005 to April 8, 2005.⁶⁷ The descriptions for Karl read ‘Not sleeping last nite . . . irritable / good day

⁶⁶ There are also four upward arrows in the box for ROM L/S (and no downward arrows in this box). However, in the course of Karl’s treatment, the chiropractors made relatively few entries in the ROM L/S box.

⁶⁷ This page includes notes from a March 30, 2005 conversation between a chiropractor and a person from Stark County Social Services. Because this note has some discussion about the chiropractor’s assessment of causation, the March 30, 2005 entry is discussed in more detail in section IV.E.2.a below.

yesterday," "Upper ext[remities] skin blotches – back pain . . . palpation of spine painful baby cries loud when touched," "Rigid lower extrem[ities]. . . . 'Doing well 'til yesterday,'" "less rigid, good mood this week, taking a few crawling steps . . . no red spots for 2 wks," "cold symptoms better . . . antibiotic / 1 wk. Augmentin . . . Discussed file with parents 'not concerned' 'You make decisions Karl's care.'" For this period, there are five upward arrows and five downward arrows. Exhibit 12 at 7.

The next page of entries begin on April 15, 2005, with a notation of "'doing so-so' – some crawling." These entries record Karl's status starting approximately three months after his January 19, 2005 vaccinations. Thus, they are relatively less germane to the question posed by the Court. Opinion and Order, 104 Fed. Cl. at 480.

2. Statements Regarding the Cause of Karl's Decline from His Treating Physicians

The next topic for which the Court ordered reevaluation was statements of treating doctors regarding the cause of Karl's decline. In this regard, the Court ordered further discussion of a chiropractor's March 30, 2005 entry, a doctor who examined Karl's MRI, and a report from Dr. Frost who examined Karl's MRIs. These are discussed in turn.

a) Chiropractor's March 30, 2005 Note

By March 30, 2005, Karl had been treated at the Pokorny Chiropractic Clinic 15 times. On March 30, 2005, a person, probably Brenda Erie, from Stark County Social Services, called the chiropractor to discuss Karl's condition. (A week earlier, Ms. Erie had called Dr. McDonough about Karl's case. Exhibit 5 at 73; exhibit 3 at 7). The reason for the call was a "poss. Adverse Rx / vaccine." The chiropractor's notes say "I responded – No." Exhibit 12 at 7.

This record does not assist the Palucks in establishing that a vaccine adversely affected Karl. The overall context suggests that, between the chiropractor and Ms. Erie, the idea that Karl could have had an adverse reaction originated with Ms. Erie. Until the discussion with Ms. Erie, the chiropractor has no notes mentioning a vaccine. To the extent that Ms. Erie was proposing an adverse reaction to a vaccine, there is no information in the record about Ms. Erie's qualifications to link a vaccine to an adverse health outcome. See 42

U.S.C. § 300aa–13(a) (stating a special master may not award compensation when claims are “unsubstantiated by medical records or by medical opinion”).

Regardless of who initially proposed the adverse reaction, the more important point is how the chiropractor replied. The chiropractor answered “No.” The chiropractor’s opinion was that Karl did not have an adverse reaction to a vaccine. The chiropractor’s opinion is the opposite of what the Palucks are asserting. See Resp’t Resp., filed June 8, 2012, at 8 n.1.⁶⁸

b) Dr. McDonough’s Referral to Neurologist in March 2005

The Court also directed consideration of Dr. McDonough’s referral to Dr. Kriengkrairut in March 2005. The context for this referral was that Dr. McDonough had seen Karl on January 19, 2005, for Karl’s one-year check-up. (It was at this appointment that Karl received the vaccinations at issue in this case.) As of that date, Karl “was rolling over and babbling but not sitting yet and not crawling much.” Exhibit 3 at 7; see also exhibit 3 at 3. Dr. McDonough referred Karl for physical and occupational therapy as well as a stimulation program. Exhibit 3 at 7.

After Dr. McDonough’s referral, the parents did not take Karl for physical and occupational therapy. See exhibit 3 at 9. Rather the parents were taking Karl to a chiropractor. See exhibit 12, passim.

It appears that in mid-March 2005, someone from the office of Stark County Social Services contacted Dr. McDonough “regarding Karl’s lack of participation

⁶⁸ If the chiropractor had provided an opinion supporting the Palucks’ claim that a vaccine harmed Karl, then that opinion would be considered as part of the record as a whole. See 42 U.S.C. § 300aa–13. The chiropractor’s training and experience to reach a medical conclusion about causation would, however, be factored into the evaluation of any such opinion. See Tiufekchiev v. Sec’y of Health & Human Servs., No. 05-437V, 2008 WL 3522297, at *11 (Fed. Cl. Spec. Mstr. July 24, 2008) (chiropractor’s “diagnosis [of petitioner’s] symptoms as post-vaccination syndrome . . . is afforded the least evidentiary weight of [petitioner’s] treating doctors” (citing Anderson v. Sec’y of Health & Human Servs., No. 06-168V, 2006 WL 5626962, at *3 (Fed. Cl. Spec. Mstr. Oct. 13, 2006); Diaz v. Shalala, 59 F.3d 307, 314 (2d Cir. 1995))).

in physical and occupational therapy.” Exhibit 3 at 7. Although the record is not entirely clear on this point, it appears that the call from Social Services prompted Dr. McDonough to call the Palucks. See exhibit 5 at 72 (noting that on March 22, 2005, Ms. Paluck returned Dr. McDonough’s call). Mr. and Ms. Paluck reported that Karl was doing “some brief crawling, not sitting on his own, leans to one side, babbling more, rash – comes & goes.” The result of this call was Dr. McDonough’s referral of Karl to Dr. Kriengkrairut. Id.

Before Dr. McDonough formally referred Karl to Dr. Kriengkrairut, Brenda Erie from Stark County Social Services called Dr. McDonough about an emergent, yet unspecified, matter. Dr. McDonough noted that he was planning an evaluation with a pediatric neurologist. Exhibit 5 at 73.

Dr. McDonough’s written referral to Dr. Kriengkrairut came on March 24, 2005. Dr. McDonough recommended “a CT scan and medical evaluation for congenital infection and inborn areas [sic, possibly errors] of metabolism.” Dr. McDonough asked that Dr. Kriengkrairut investigate “etiology of [Karl’s] developmental delay and hypertonicity.” Exhibit 3 at 7.

There was relatively little testimony about the significance of Dr. McDonough’s referral to a pediatric neurologist. Dr. Frye stated Dr. McDonough wanted additional testing, including a CT scan. Tr. 107:4-13. This testimony is certainly correct because it restates what is clearly in the medical record.

What is less clear is why Dr. McDonough made a referral to a pediatric neurologist in March 2005, when Dr. McDonough did not make a similar referral in January 2005. Dr. McDonough did not explain his motivation in his referral. Thus, a certain amount of inductive reasoning is needed. Arguably, Dr. McDonough’s referral could reflect a concern that Karl’s condition is either not improving as quickly as Dr. McDonough would like or worsening.⁶⁹ Karl’s

⁶⁹ The Palucks, however, have not made this argument. In their post-trial brief, the Palucks mention Dr. McDonough’s referral only in passing. See Pet’r Posthr’g Br., filed Feb. 18, 2011, at 12 (noting Dr. McDonough sought “an evaluation and medical investigation into Karl’s developmental delay and hypertonicity”). In their reply brief, the Palucks do not discuss Dr. McDonough’s referral. See Pet’r Resp. to Resp’t Posthr’g Br., filed Mar. 11, 2011, at 18 (discussing medical records for March and April 2005 without mentioning referral). Even after the Court’s Opinion and Order in which the Court instructed

(. . . continued)

apparent lack of developmental progress may have alerted Dr. McDonough to consider whether Karl had a neurologic disease that a pediatric neurologist could diagnose. Another explanation, which is not inconsistent with the first reason, is that Dr. McDonough was frustrated that the Palucks were not following his recommendations for physical therapy, occupational therapy, and a stimulation program for Karl. At different points in his records, Dr. McDonough comments that Karl is not receiving the services he recommended. Dr. McDonough, therefore, may have seen the referral to a specialist as an opportunity for that doctor to reinforce Karl’s need for therapy. Since there is no testimony from Dr. McDonough about his reason(s) for the referral to the pediatric neurologist, any conclusion is necessarily tentative and speculative.⁷⁰

c) Report from July 22, 2005 MRI

The Court also ordered reconsideration of the report interpreting Karl’s July 22, 2005 MRI. Dr. Frost, from the Children’s Hospital in St. Paul, Minnesota, ordered this MRI for Karl. The doctor who dictated and released the report was Dr. Theodore J. Passe. Dr. Passe’s impressions included “[m]oderate cerebral atrophy has developed since the last exam with further thinning of the corpus callosum” and “[f]indings are consistent with a progressing leukodystrophy (consider hereditary, toxic, or metabolic etiologies).” Exhibit 11 at 91-92.

Two aspects of this report merit additional attention – “further thinning” and “toxic or metabolic etiology.”

Further Thinning

Concerning Dr. Passe’s statement that the July 22, 2005 MRI showed “further thinning,” the Court stated that “[t]he word ‘further’ suggests that the corpus callosum was already thin by April 27, 2005, and thus had begun to thin, or was thin, even earlier than that.” Opinion and Order, 104 Fed. Cl. at 479. The Court additionally cited a portion of Dr. Frye’s testimony. The undersigned asked

consideration of Dr. McDonough’s referral to the pediatric neurologist, the Palucks did not comment on this referral directly. See Pet’r Status Rep’t, filed May 7, 2012, at 6.

⁷⁰ The parties declined to offer additional testimony.

Dr. Frye what he thought was happening to Karl between January and March / April. In this context, Dr. Frye stated that Karl's worsening

would start at a cellular level, and then start to become more and more clinical, and one of the things I kind of base that on is the first MRI seemed equivocal. Right at first, it was read as normal, and then it's read abnormal, and that's not that unusual sometimes when you go back.

But that suggests this process was just starting, so over several months, you know, you started getting it at the cellular level, and then it was just beginning to be on the point where you can actually see it on MRI, which means it has to be pretty severe.

Tr. 232:5-15.

Dr. Frye's reasoning that a showing of an abnormality on the April 27, 2005 MRI means that the abnormality must have existed before the scan was performed is certainly correct. See W.C. v. Sec'y of Health & Human Servs., 100 Fed. Cl. 440, 451-53 (2011) (finding that special master was not arbitrary in finding that non-enhanced lesions on MRI was evidence that petitioner suffered from non-eloquent multiple sclerosis before the vaccination), aff'd, 704 F.3d 1352 (Fed. Cir. 2013). Dr. Frye, however, does not offer a discrete opinion as to when the corpus callosum began to thin.⁷¹

When asked about the April 2005 MRI, which showed abnormalities in Karl's white matter, Dr. Snodgrass testified "[o]f course we don't know when that injury occurred." Tr. 484:19-20. The Palucks' attorney, who was cross-examining Dr. Snodgrass at the time, followed this answer by asking:

Q: Well, I believe it was Dr. Frye's testimony that the evidence – that the scan – characteristics of the scan would indicate that that injury was close in time to the MRI, which would put it within the time frame after the vaccine; wouldn't it?

A: Maybe that's Dr. Frye's opinion but that's not mine. I have seen similar scans in people who had prenatal infections with the same kind of white matter abnormality, six or 12 months later.

⁷¹ Dr. Frye states that the process may have been taking place for "several months" without explaining how long "several months" is.

Tr. 484:21 to 485:4.

In an ideal circumstance, an MRI where Karl’s brain appeared “normal” would be available for the experts to reference in their effort to date the onset of Karl’s neurological injury. Unfortunately, this is not the case. Instead, the experts’ ability to offer any definitive opinion as to the onset is severely constrained by the available evidence.

In sum, the April 27, 2005 MRI provides radiographic information that one structure of Karl’s brain was not normal on that date. But, the next inference – deciding when the corpus callosum started to thin – necessarily requires some speculation. The Palucks have not established that Dr. Frye’s conclusion that Karl’s corpus callosum started to thin after the vaccination is more likely than Dr. Snodgrass’s conclusion that the corpus callosum could have been thin before the vaccination. The finding that Karl was evidencing CNS dysfunction before vaccination, however, weighs against Dr. Frye’s view.

Toxic or Metabolic Etiology

The Court also directed consideration of Dr. Passe’s impression that Karl’s July 22, 2005 MRI was “consistent with a progressing leukodystrophy (consider hereditary, toxic, or metabolic etiologies).” Exhibit 11 at 91-92. This statement is not persuasive evidence that a vaccine harmed Karl for two reasons.

First, Dr. Passe stated that the etiology could be metabolic and Karl was found to have a metabolic disorder. Karl’s mitochondrial disease is a dysfunction in Karl’s metabolism. Thus, of the three possibilities Dr. Passe listed, “metabolic” seems most likely to fit Karl’s situation.

Second, although the term “toxic” is broad enough to include an injury caused by a vaccine, this category includes other sources as well. A prominent non-vaccine potentially “toxic” substance is the anesthesia Karl received before the April 27, 2005 MRI. See Tr. 561:4 (the scan “required him to receive general anesthesia”). Dr. Snodgrass proposed that the anesthesia could have harmed Karl. See Tr. 582:5-11.

Dr. Frye did not say that Dr. Passe’s statement that Karl’s progressing leukodystrophy could have a “heredity, toxic or metabolic” etiology meant that Dr. Passe was stating that a vaccine caused the leukodystrophy that Dr. Passe

identified in Karl. The only testimony from Dr. Frye about Dr. Passe's reference to a toxic etiology in the July 22, 2005 report was as follows:

Q: And the radiologist makes a suggestion for considering the etiology of this change in his white matter. What was that suggestion that the radiologist made?

A: So he was suggesting hereditary abnormalities, toxic abnormalities, and metabolic etiologies.

Tr. 118:7-11. While the Palucks have cited Dr. Passe's July 22, 2005 report as a statement of a treating doctor showing that the reason for Karl's decline was the vaccination, see Pet'r Resp. to Resp't Posthr'g Br., filed Mar. 11, 2011, at 20, the Palucks' argument is really an attorney's argument. The argument is not persuasive because the Palucks have not addressed the other possible causes listed by Dr. Passe (metabolic) and have not explained why the "toxic" etiology means "vaccine." See, e.g., Tr. 121:16-24 (Frye direct examination) (Q: "[W]hen you're mentioning the term "toxic event," that is the toxic events occurring intracellularly, not necessarily that it is a toxin like thimerosal or something such as that." Dr. Frye: "No. You're absolutely right. I'm sorry.").

d) Dr. Frost's December 5, 2005 report

In a footnote, the Court mentioned that the undersigned did not discuss Dr. Frost's December 5, 2005 report. Opinion and Order, 104 Fed. Cl. at 479 n.29. This report followed Karl's hospitalization in October 2005.

Although this report summarized Karl's history, the focus appears to be on the report from an MRI conducted on October 27, 2005. Essentially, this report compares the results of the three MRIs. It states that between the first MRI (in April) and the second MRI (in July), Karl deteriorated. Between the second MRI and the third MRI (in October), Karl remained about the same. Neither Dr. Frye nor Dr. Snodgrass testified that the third MRI offered any meaningful information about the cause of Karl's neurologic problem. Similarly, the parties have not presented any argument based on the third MRI in their post-hearing briefs, including the briefs submitted after remand.

3. Conclusion

The December 14, 2011 decision found that Karl’s post-vaccination developmental decline was not linear, as the Palucks argued. 2011 WL 6949326, at *23. The Court vacated this finding for additional consideration. After reevaluating the evidence in accordance with the Court’s instructions, the special master again concludes that Karl’s deterioration was non-linear.

The Federal Circuit has recently explained that part of the Althen prong 2 analysis may consider whether the expert’s “theory accounted for [the vaccinee’s] injury.” Hibbard, 698 F.3d at 1364. Here, Dr. Frye’s theory predicts that the vaccine would cause a dramatic and continual deterioration, beginning within two to three weeks after receipt. See Tr. 126:14-23 (“immunizations . . . result in immune activation, which causes a fever . . . , followed by irritability for several days to weeks and then loss of skills which continues from weeks to months”), 145:12-13 (“usually reactions happen within two weeks of having a vaccine”), 132:6-12 (initiation of the downward spiral “happens probably within a week of the inciting event”). And, Dr. Frye testified that Karl responded in accordance with his theory. Tr. 657:10-19 (subsequent to vaccination “he has devastating regression that continues until April, and continued after that with the development of seizures and him continuing to lose function”), 663:20 to 664:1 (“the vaccine triggered a process that was self-perpetuating and caused a downward spiral to continue to damage the body and cause cell death”). Karl, however, did not decline as expected in the relevant time. Thus, the Palucks have failed to meet their burden regarding Althen prong 2, which corresponds to Loving prong 5.

F. Loving Prong 6: What is a Proximate Temporal Relationship between the Vaccination and the Significant Aggravation?

The last element in the six-part Loving test has origins as the third prong of Althen. As stated by Loving, this element is “a showing of a proximate temporal relationship between the vaccination and the significant aggravation.” Loving, 86 Fed. Cl. at 144. Based upon Bazan v. Sec’y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008), the December 14, 2011 decision divided this element into two components: “(a) the timeframe for which it is ‘medically acceptable to infer causation,’ and (b) the onset of the condition for which petitioner seeks compensation.” 2011 WL 6949326, at *24. The Court’s Opinion and Order did not reject this organizational construct. 104 Fed. Cl. at 480-83.

The December 14, 2011 decision analyzed the evidence for each of these components and found that the appropriate medical interval was two weeks and that Karl did not manifest neurodegeneration until after two weeks. 2011 WL 6949326, at *26-28. The Court's Opinion and Order, however, vacated both findings, stating that these findings were "arbitrary and capricious." 104 Fed. Cl. at 483. Although the Court vacated the findings in the December 14, 2011 decision, the Court did not state that the December 14, 2011 decision failed to discuss relevant evidence. The Court, as noted previously, did not make any findings of its own.

1. Medically Acceptable

a) Standards for Adjudication

On occasion, the Federal Circuit has examined how special masters have implemented the third prong of Althen. One example is Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352 (Fed. Cir. 2006). There, the Federal Circuit stated that "[e]vidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis." Id. at 1358.

The Federal Circuit viewed how the special master had examined the evidence. The Federal Circuit quoted the special master's decision as stating "Petitioners provide no objective evidence indicating an appropriate time frame in which Still's disease will manifest subsequent to a triggering event." Id. at 1359 (quoting Pafford v. Sec'y of Health & Human Servs., No. 01-165V, 2004 WL 1717359, at *7 (Fed. Cl. Spec. Mstr. July 16, 2004)) (internal quotation marks omitted). The Paffords' evidence on this point was lacking because one expert (Dr. Levin) did not provide any evidence on this point and the other expert (Dr. Geier) was not persuasive. The special master found Dr. Geier's testimony insufficient because, in part, the scientific literature he relied upon did not "show the specific temporal relationship for Still's disease[.]" only "the temporal relationship for arthralgia episodes and joint syndromes in general[.]" Id. (citing 2004 WL 1717359, at *7 n.42). Under its standard of review, the Federal Circuit did not identify a "reversible error" in the special master's decision. Id.

Another example of a Federal Circuit case involving the appropriate medical interval is Bazan, 539 F.3d 1347. There Ms. Bazan claimed that a tetanus toxoid-diphtheria vaccine caused her to suffer acute disseminated encephalomyelitis

(“ADEM”) approximately 11 hours later. The special master accepted the testimony of the government’s expert who testified that 11 hours was an insufficient amount of time for the vaccine to have caused the ADEM. Id. at 1349-50. The special master rejected the testimony from Ms. Bazan’s treating neurologist, who acted as her expert witness, for two reasons. First, her neurologist relied upon case studies that did not connect a vaccination and ADEM in as little as 11 hours. Second, her neurologist’s attempt to draw an analogy between diseases of the peripheral nervous system (“PNS”), which might occur within 11 hours, and diseases of the CNS, such as ADEM, was unpersuasive because the myelin in the PNS differs from the myelin in the CNS, making “the timeframes of PNS disorders . . . not probative of timeframes in CNS disorders.” Id. at 1353; see also Bazan v. Sec’y of Health & Human Servs., No. 03-620V, 2006 WL 5616947, at *5-8 (Fed. Cl. Spec. Mstr. Feb. 7, 2006). When the Federal Circuit reviewed the special master’s finding, the Federal Circuit ruled that it could discern no error in how the special master evaluated this evidence. 539 F.3d at 1354.

A close reading illuminates several points. First, a special master is not required to find a petitioner’s evidence that the interval between vaccination and the onset of the condition for which the petitioner seeks compensation is “medically acceptable.” In Pafford, Dr. Geier testified that the relationship was “medically acceptable.” 451 F.3d at 1359 (citing Trial Tr. 39-40). In Bazan, the treating neurologist “defend[ed] her conclusions with strong conviction.” 2006 WL 5616947, at *8. Nevertheless, the special master did not deem that the petitioners in either case had met their burden of establishing the proximate temporal interval based upon the expert’s testimony by itself.

Second, rather than simply looking at whether the petitioner had presented any relevant evidence, a special master may explore whether the expert’s opinion was based upon “reliable medical or scientific evidence.” Bazan, 2006 WL 5616947, at *8. An assessment of the quality of the purported reasons for the medically appropriate interval is consistent with other aspects of the evidence-weighting function. See Vaccine Rule 8(b)(1); Moberly, 592 F.3d at 1325 (“Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.”). Whether the petitioner’s expert asserted that medical articles supported the expert’s opinion was not dispositive. The Federal Circuit has approved a methodology in which the special master considered all evidence (including evidence offered by the Secretary), weighed the

evidence, and reached a conclusion about what testimony was more probative. Bazan, 539 F.3d at 1354.

b) Evidence

Here, the Palucks rely upon three passages from Dr. Frye's testimony (Tr. 127-32, 231-32, 659).⁷² They buttress this testimony by citing two articles, the Poling article and the Shoffner article. Pet'r Posthr'g Br., filed Feb. 18, 2011, at 21-22; see also id. at 29-31.

Dr. Frye opined that an adverse reaction to a vaccine "would be thought to appear sometime probably within a week of receiving the vaccine. It may not be immediate." Tr. 127:21-23. Consistent with his general theory, Dr. Frye stated that adverse reactions to vaccines "lead to this metabolic decompensation, which is an ongoing process, and if it's not interrupted, it's going to continue until it burns itself out." Tr. 128:6-9. When asked how long it would take for the child to express neurodegenerative changes clinically, Dr. Frye provided an answer that suggested the timeframe is not bound. He stated the clinical manifestation of neurodegeneration is

probably going to depend on the severity and type of mitochondrial disorder, so what we try to describe as a cascade of events that are ongoing, so I try to make analogies to some of the other diseases, such as Parkinson's disease and Alzheimer's disease that people have talked about, this relation between oxidative stress and mitochondrial disorder, and also the other thing, aging.

Well, aging is a process that happens over decades, you know. The process that happens in mitochondrial – the interaction between mitochondrial disorders and oxidative stress and some of the neurodegenerative diseases also happen over years or decades, too. So it's not unreasonable to think that, with a mild mitochondrial disorder, that you can have something that spans, you know, spans

⁷² Some of this testimony pertains to what happened to Karl. Those portions are discussed in the following section. Likewise, the Palucks' reply brief primarily discusses when Karl had problems, not the medically appropriate interval. See Pet'r Resp. to Resp't Posthr'g Br., filed Mar. 11, 2011, at 16-19.

years, you know, whereas with a more severe mitochondrial disorder, that it could happen within days or weeks or months.

Tr. 128:22 to 129:14. Dr. Frye summarized his position with regard to the appropriate medical interval by, again, identifying two different periods. He stated:

I think there's two periods of time that we have to look at: one, when the inciting event caused the immune system to get to the point where it initiated the cascade of events that caused dysfunction between the mitochondria and oxidative stress, and then this process of this kind of – this spiral of activity, this downward spiral of activity between the mitochondria and oxidative stress, which occurs on a different time scale.

So, one, there's the time scale of actually initiating the dysfunction or this downward spiral, and then the time in which this downward spiral occurs. And it appears reasonable to suggest that the first portion happens probably within a week of the inciting event, and then it's reasonable to think the second portion is going to depend on the underlying dysfunction in the mitochondria.

Tr. 131:23 to 132:12.

In regard to the second phase, the period in which the damage to mitochondria is becoming manifest, Dr. Frye referenced an additional set of papers. He testified:

[Y]ou actually start stressing an already vulnerable mitochondria which then creates more reactive oxygen species which then damages itself more, and this process goes on . . . and gets worse and worse over time until the mitochondria actually then signals cell death. And if we look at the experimental uveitis papers there is some very nice data that show that early on the changes are isolated to the mitochondria but that after some time these changes can then become so severe that then they signal apoptosis or programmed cell death after the degenerative changes occur within the mitochondria.

Tr. 660:24 to 661:11.

The Secretary addressed these arguments through Dr. Snodgrass's testimony and in her brief. See Resp't Posthr'g Br., filed Feb. 18, 2011, at 46-49. In addition, the Secretary cited an article by Edmonds (Exhibit 21, tab D, Joseph L. Edmonds et al., The Otolaryngological Manifestations of Mitochondrial Disease and the Risk of Neurodegeneration with Infection, 128 Archives of Otolaryngology - Head & Neck Surgery 355 (2002)), which Dr. Frye cited but did not discuss. Id. at 50-51.

Dr. Edmonds and his colleagues identified 40 patients who had mitochondrial diseases. The researchers collected information, via interview and medical chart review, about the number of infections, episodes of acute otitis media, and episodes of neurodegeneration from 27 patients. The researchers explained their findings:

The timing of the infection and neurodegenerative event varied. In a few patients (3/13), the neurologic setback occurred early in the course of infection. In most patients (10/13), the neurologic event occurred 3 to 7 days after the onset of infection and frequently appeared at a time when the infection was resolving. This pattern of delayed neurodegeneration in association with infection is depicted graphically in Figure 3.

Exhibit 21d at 6. Figure 3 and its caption are reproduced below:

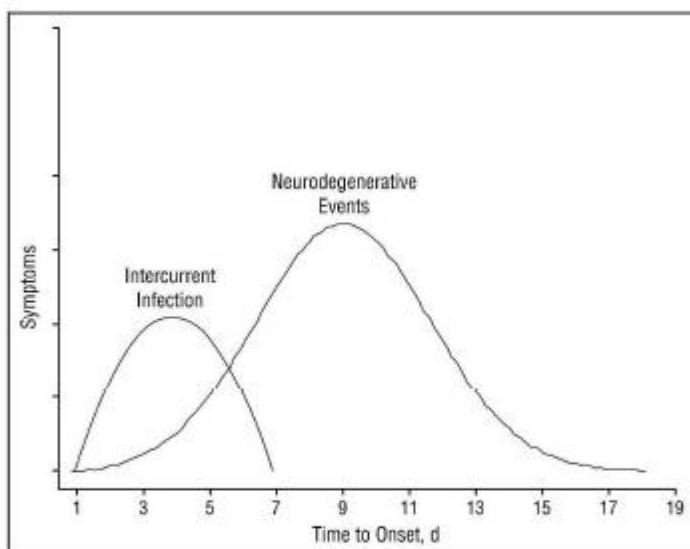


Figure 3. Timing of infection-associated neurologic setbacks in patients with mitochondrial disease. The temporal delay in the onset of neurodegenerative events associated with infection in most patients was similar to that described in Reye syndrome by Partin.¹²

Exhibit 21d at 7.

The Court interpreted Figure 3 as showing “a bell curve peaking at nine days and representing that the tails on either side of the peak ranged from one day at one side to nineteen days on the other side.” Opinion and Order, 104 Fed. Cl. at 481.

This article is useful because the subjects are people with mitochondrial disease. Therefore, they have at least some similarity to Karl, who also has a mitochondrial disease. By retrospective chart review, the researchers looked for evidence of “neurodegeneration,” which is, nominally, the condition that Dr. Frye says that Karl has.⁷³ One difference between the people in the Edmonds study and Karl is that the patients in the study were infected, while Karl received a vaccination. Dr. Snodgrass explained that “the Edmonds paper does not deal with vaccine injuries, it deals with changes in the status of patients with mitochondrial disease with infection. That’s not the same as a vaccine, but it provides some guideline.” Tr. 524:1-5.⁷⁴ Dr. Snodgrass continued, “So if the change did not come within a few weeks, we have to say there’s no evidence that the vaccine caused that problem in this particular person.” While Dr. Snodgrass discussed the Edmonds paper and viewed it as a “guideline,” the Palucks did not solicit any comments from Dr. Frye during his testimony on redirect, even though it was Dr. Frye who originally cited the paper.⁷⁵ Dr. Frye, however, appears to offer his implicit acceptance of this timeframe in the following exchange on redirect.

Q: I’d like to talk about the medically acceptable time frame. Dr. Snodgrass said in his testimony that he would need to see timing of regression within a few weeks after receipt of vaccines, and that’s

⁷³ Because Edmonds did not define the term “neurodegeneration,” it is not absolutely clear whether Karl’s case would have fit the Edmonds criteria. The decision assumes that Karl would.

⁷⁴ In the transcript, “Edmonds” is sometimes produced as “Edmunds.” This decision corrects the transcript without notation.

⁷⁵ See Tr. 619:24 (petitioners’ counsel incorrectly asking about the Edmonds paper that “was written in the context of sepsis”).

at transcript page 526 to 527^[76]. . . . [B]ased upon the evidence of scientific and medical literature and the clinical course that we've just reviewed with Karl, was Karl's regression within a medically accepted period of time to be . . . caused by his January 2005 immunizations?

A: Most definitely. [W]e seem to see the pattern of regression . . . of fever, irritability . . . We see spasticity emerging [in] Karl on February 11th, which is about *three weeks* after he has the vaccines. So we have documented evidence that within *three weeks* he actually has neurological changes in his motor system.

Q: Is that consistent with your medical theory of causation?

A: Yes it is, it very much is.

Tr. 659:14 to 660:10 (emphasis added); see also Tr. 666:4-7 (Dr. Frye: I think that we've actually shown that we have documented evidence of neurological regression within *three weeks* of receipt of the vaccine." (emphasis added)). Because of the similarities between the sequence of events Dr. Edmonds identified and the sequence of events in Karl's life proposed by Dr. Frye, Dr. Snodgrass's point that Edmonds can serve as a "guideline" for anticipating whether a vaccine adversely affected a person with a mitochondrial disease is well-taken.

Another article that discusses possible adverse effects of vaccines in people with mitochondrial disorders is the Shoffner paper. Dr. Shoffner and his colleagues wanted to explore "the relationship of autistic regression with fever and vaccination in autistic spectrum disorder patients" who essentially displayed a problem in how they produced energy in their cells. Dr. Shoffner's team retrospectively reviewed charts and identified "28 patients who met diagnostic criteria for autism spectrum disorders and diagnostic criteria for mitochondrial diseases." Dr. Shoffner also looked to see whether any of these patients suffered "autistic regression," which, for this study, was defined as "loss of developmental skills that included speech, receptive skills, eye contact, and social interests in individuals <3 years of age." Exhibit 21, tab Z (John Shoffner et al., Fever Plus Mitochondrial Disease Could Be Risk Factors for Autistic Regression, *J. Child Neurol* (2009)) at 2.

⁷⁶ This transcript citation is to an exchange that follows Dr. Snodgrass's discussion of the Edmonds paper, where the undersigned sought to "distill some of the factors" that Dr. Snodgrass would look for with regard to timing and whether a "vaccine has caused neurological problems."

Of the 28 patients, 17 (approximately 60%) had autistic regression. Dr. Shoffner found that in 12 cases, the autistic regression occurred within two weeks of having a fever. Furthermore, in four of those 12 cases, Dr. Shoffner stated that the fever, which preceded the autistic regression, was a “febrile response to vaccination.” The article explains that details about the duration of the fever were “difficult to ascertain because patients were usually managed in the home. The duration of the fever appeared to extend for at least 3 to 7 days in conjunction with decreased oral intake.” *Id.* at 3.

For purposes of evaluating the evidence regarding the interval between vaccination and significant aggravation, the sixth Loving prong, Dr. Shoffner’s definition of an autistic regression in the context of fever is important. Dr. Shoffner selected “2 weeks” as the period to investigate. Dr. Shoffner’s use of that period of time suggests that he would consider that a regression occurring within two weeks of a fever could be caused by the fever.

This same period was also used by researchers investigating experimental autoimmune uveitis through animal models. In various articles, the Lewis rats experienced the adverse effect of an injection within 14 days of the injection. See Exhibit 21, tab J (Rahul N. Khurana et al., Mitochondrial Oxidative DNA Damage in Experimental Autoimmune Uveitis, 49 (8) Investigative Ophthalmology & Visual Sci. 3299(2008)) at 3302; exhibit 37, tab B (Sindju Saraswathy & Narsing A. Rao, Photoreceptor Mitochondrial Oxidative Stress in Experimental Autoimmune Uveitis, 40 Ophthalmic Res. 160 (2008)) at 160; exhibit 37, tab C (Guey-Shuang Wu et al., Photoreceptor Mitochondrial Tyrosine Nitration in Experimental Uveitis, 46(7) Investigative Ophthalmology & Visual Sci. 2271 (2005)) at 2271-72; see also Tr. 301:10 (Dr. Snodgrass’s testimony that damage in the autoimmune uveitis animal experiments occurs “early on”); 487:23 to 488:10 (same); 605:2 to 606:22 (Dr. Frye’s testimony discussing the animal studies); 742:25 to 743:2 (Dr. Frye’s testimony that “the processes that can occur as a result of a vaccination do not have to be immediate and can occur weeks afterward” (citing the Wu article)). The results of these experiments suggest that if a human being is going to have an adverse reaction, then the time for the adverse reaction would be within 14 days.⁷⁷

⁷⁷ Because the Lewis rats are (obviously) not human, conclusions drawn from an animal model would need a step of extrapolation to humans. However, Dr. Frye cited these articles as supporting his opinion. See exhibit 21

(. . . continued)

The remaining article is about Hannah Poling. The authors report that Hannah received a set of vaccinations and developed a fever within 48 hours. She had a low-grade intermittent fever for the next 12 days. Six days after immunization, she lost the ability to climb stairs, and four days after that she developed a macular rash beginning in the abdomen. She later lost the ability to communicate, although years later she had improved to some degree. Exhibit 21, tab Q (Jon S. Poling et al., Developmental Regression and Mitochondrial Dysfunction in a Child with Autism, 21(2) J. Child Neurology 170 (2006)).

To the extent that a case report about a single person provides information about the period in which the medical community would accept an inference of causation, Hannah Poling lost a skill (climbing stairs) six days after vaccination. She displayed symptoms of a stimulated immune system (a fever and a rash) within two weeks of the vaccination. She also showed evidence of impairment in her extremities. While she may have deteriorated further, special masters focus on the onset of the problem, not the duration of the problem. See, e.g., Doe/11 v. Sec'y of Health & Human Servs., No. 99-212V, 2008 WL 4899356, at *30 (Fed. Cl. Spec. Mstr. Oct. 29, 2008) (rejecting petitioners' claim under prong 3 because the onset of clinical symptoms was not within the expected time frame), mot. for rev. denied, 87 Fed. Cl 1 (2009), aff'd, 601 F.3d 1349 (Fed. Cir. 2010); Pafford, 2004 WL 1717359, at *7 ("the timing of onset of Still's disease subsequent to a triggering event is not a telling characteristic of the disease. Accordingly, absent an appropriate time frame, the Court cannot find the mere temporal proximity of the vaccination and injury dispositive"), mot. for rev. denied, 64 Fed. Cl. 19 (2005), aff'd 451 F.3d 1352 (Fed. Cir. 2006).

(supplemental expert report); exhibit 30 (supplemental report explaining relevance of approximately 20 articles filed after first hearing); Notice of Filing Exhibits, filed October 15, 2010 ("Exhibits 37a-f & h address the[] concerns of Dr. Snodgrass.").

In discussing the Palucks' evidence relating to the reliability of the theory that vaccines can produce an excessive amount of oxidative stress at least in people with mitochondrial defects, the December 14, 2011 decision found that the experimental autoimmune uveitis articles did not support the reliability of that aspect of petitioners' case. See 2011 WL 6949326 at *13, 17. The Court's Opinion and Order, however, appears to indicate that the rejection of the articles vis-à-vis the reliability of the oxidative stress theory means that the articles also must be rejected vis-à-vis the timing. See 104 Fed. Cl. at 481 n.31.

The December 14, 2011 decision found that the appropriate temporal interval was two weeks. The Court vacated this aspect. Upon further reflection, especially in light of the interpretation of Edmonds's figure 3, which extends a tail of symptoms of neurodegeneration to 19 days, the undersigned finds that the appropriate temporal interval extends to three weeks.

2. Onset of Karl's Neurodegeneration

The December 14, 2011 decision found that Karl's neurodegeneration did not start within the time expected by the medical community. Rather, the decision found that Karl's significant decline started in April 2005. The Court vacated this finding, ordering re-examination of Karl's medical records, including his chiropractor's records and Dr. Frye's testimony.

The important time is within three weeks of January 19, 2005. This date is February 10, 2005.⁷⁸ Thus, for the Palucks to meet their burden of proof they must show that Karl manifested signs or symptoms of neurodegeneration within this timeframe. As a preliminary matter, it is worthwhile to explain, again, what "neurodegeneration" is because the definition of that term will guide the following assessment of the medical records.

a) Neurodegeneration

Dr. Frye did not define "neurodegeneration," although his reports state that Karl suffered from neurodegeneration. Exhibit 16 at 1; exhibit 21 at 3. However, Dr. Frye did define the term "regression," which is similar to neurodegeneration.

⁷⁸ Although the Court characterized the finding that the medical community would accept two weeks (now modified to three weeks) as establishing a "hard and fast" period, the undersigned does not view the outside marker as an unsurpassable boundary. For example, the December 14, 2011 decision considered information about Karl's condition as the chiropractor reported it on February 7 through April 2, 2005, even though these appointments occurred outside of the temporal window found in the decision. In practical and hypothetical terms, given the same record but that Karl had his first seizure on the 22nd day after vaccination, the petitioners would have met their burden of proof regarding the temporal association prong. However, Karl's records did not show significant declines until months after the vaccination, making any assessment of shades of grey unnecessary.

Regression means that a person becomes unable to do something that the person previously could do. Tr. 117:4-10; see also exhibit 21, tab Z (Shoffner) at 2 (defining autistic regression) and Tr. 194-96 (discussing Shoffner's definition of autistic regression even though Karl is not autistic). Dr. Snodgrass stated that a loss of skill constituted regression. Tr. 430:16-20.

A definition of "neurodegeneration" comes from Dr. Snodgrass. He testified that he understands the term "as meaning that there is a decline – a continuing, it keeps going on, decline in the function of the brain in multiple areas." Tr. 531:8-10. Dr. Snodgrass provided a similar definition of "neurodegenerative disease." He stated that it means "a progressive disease where the brain gets worse and worse." Tr. 502:22-23.

Consequently, it is important to review the information available about Karl to see if he was losing any functions between January 19, 2005 and February 10, 2005.⁷⁹

b) Medical Records

Between January 19, 2005, and February 10, 2005, there are two contemporaneously created sources of information about Karl: the daycare records and the chiropractor's records.

Daycare records and testimony thereon

The records from daycare (exhibit 22) report the following:

- January 21, 2005: Karl had a fever 101.5.
- January 24, 2005: Karl was "very fussy – didn't eat very good. Likes his blanket[,] wants his bottle."
- January 25, 2005: Karl "[d]idn't eat very good. Fussy."

⁷⁹ Unfortunately, some testimony was vague about when certain events occurred. For example, the Palucks' counsel asked Dr. Frye "in Karl's case, his loss of skills progressed from sometime after January 19, 2005, to July 2005, when he had regressed to the point of approximately a one-month-old." To which, Dr. Frye simply responded "Exactly." Tr. 126:24 to 127:2. This exchange is not helpful because Dr. Frye does not state when the regression started.

- January 26, 2005: “Fussy again[,] very tired” and Karl “talked about a cup.”
- January 28, 2005: Karl fever 101.3. Very fussy – act tired all day.
- January 31, 2005: Karl act very tired [and] fussy. He has spots all over his arms and legs again.⁸⁰
- February 1, 2005: Sheila from the Kids Program came to work with Karl [and] commented that Karl acts very tired and wants to be held.
- February 2, 2005: Parents comment about Karl not sitting up yet.
- February 3, 2005: Sheila said Karl did very good today. Karl eats 3 to 5 bites of food at meals then wants his bottle.
- February 4, 2005: Fussy again – Acts like he is tired.
- February 7, 2005: [Ms. Paluck] took Karl to the chiropractor today.
- February 8, 2005: Karl not very content not sleeping very long 1/2 [hour] at a time. Tries to crawl pulling his body.

Following the February 8, 2005 entry, there is a note from the child care provider. It states “[t]he fussy or crabiness maybe due to tired, hungry[,] maybe teeth or gums hurting. Or he could be in pain and be angry for not being able to get around. In classes that I have taken[,] they say every child develops at their own rate.” This entry concludes the daycare records that the Palucks submitted.⁸¹

To Dr. Frye, Karl’s irritability and lethargy were evidence that Karl suffered an encephalopathy. Tr. 193:10-25, 702:23-704:2; see also Tr. 126:15-127:2. “Encephalopathy” is a broad term, meaning, in common medical parlance, “any degenerative disease of the brain.” Dorland’s at 614.

⁸⁰ Both experts stated that spots on Karl’s body probably indicated another recurrence of the erythema multiforme. Tr. 645:2-10 (Dr. Frye), 804:4-11 (Dr. Snodgrass).

⁸¹ Dr. Snodgrass stated “we have a narrow slice of evidence. For instance, I would like to know about the fever charts, those infant-grams for September, October, November and December. I don’t think it’s proper to give us temperatures only during the month of January.” Tr. 256:8-12. Again, the Palucks were ordered on July 22, 2011 to file any additional daycare records, but they reported that there were none. Pet’r Status Rep’t, filed Aug. 22, 2011. See footnote 28 above.

As every parent knows, irritability and lethargy even in the presence of a fever do not always foreshadow an encephalopathy, or in non-medical terms, a “degenerative disease of the brain.” Dr. Frye stated that Karl’s tiredness, irritability, and decrease in appetite were “not specific.” Tr. 68:9. Dr. Snodgrass stated that Karl “did not have [an] encephalopathy in January.” Tr. 389:2-3.

Regarding the question of whether Karl had a vaccine-induced encephalopathy in January 2005, Dr. Frye’s opinion was less persuasive than Dr. Snodgrass’s opinion. Dr. Frye did not explain why Karl’s relatively minor and relatively common problems (irritability, two instances of fever, and decreased appetite) constituted a more severe process, an encephalopathy.⁸²

In contrast, Dr. Snodgrass pointed out that Karl was well enough to attend daycare. Tr. 297:7-8, 344:18. Dr. Snodgrass also noted the difference in the frequency of visits to health care providers. For the remainder of January after the vaccination and throughout February 2005, Karl’s parents did not take him to a medical doctor’s office. This absence of medical appointments contrasts with Karl’s situation “between November and December [2004] when he was often seeing the doctors, either in Bismarck or at the Dickinson Clinic or his parents were telephoning them.” Tr. 341:23 to 342:1; accord Tr. 336:19-22. From this difference, Dr. Snodgrass drew the following conclusion: “So I have every reason to believe that his parents are attentive to his needs, so I have to conclude that he was more sick in November and December than he was in January and February.” Tr. 342:2-5. Dr. Frye did not persuasively refute this point. For these reasons, the evidence does not preponderate in favor of finding that Karl had a new encephalopathy between January 19, 2005 and February 10, 2005 that aggravated his condition.⁸³

⁸² For academic support for the proposition that fever is relatively common in children, see exhibit J (Ellen R. Wald et al., Frequency and severity of infections in day care: Three-year follow-up (pt. 1), 118(4) J. Pediatrics 509 (1991)); Tr. 291, 345 (discussing Wald). See also exhibit L (S. Michael Marcy et al., Fever as an adverse event following immunization: case definition and guidelines of data collection, analysis, and presentation, 22 Vaccine 551 (2004)) at 2 (noting the “known high background rates . . . of fever); Tr. 347 (discussing Marcy).

⁸³ Although Dr. Frye introduced the question of encephalopathy, whether (and when) Karl suffered an encephalopathy is not quite the right issue. The issue
(. . . continued)

Although Dr. Snodgrass opined that Karl's irritability and other problems did not constitute an encephalopathy, Dr. Snodgrass recognized that the irritability and other problems could be symptoms of a significant problem. See Tr. 291:13-14 (irritability "might indicate something serious"). Vaccine case law, too, provides examples of histories in which a relatively minor problem (such as excessive eye blinking) is understood, in retrospect, to be the beginning of a more serious problem (such as a seizure disorder). See Markovich v. Sec'y of Health & Human Servs., No. 03-2015V, 2005 WL 6117470 (Fed. Cl. Spec. Mstr. July 22, 2005), mot. for review denied, 69 Fed. Cl. 327 (2005), aff'd, 477 F.3d 1353 (Fed. Cir. 2007). Consequently, the chiropractor's records will be reviewed, even though, with one exception, the visits took place outside of the appropriate medical interval.

Chiropractor's Records

Karl's parents began taking him to see a chiropractor on February 7, 2005. Not much additional information can be gleaned from the intake forms and neither Dr. Frye nor Dr. Snodgrass discussed the February 7, 2005 visit specifically. See exhibit 12 at 1-6. The chiropractor, however, reports that on February 9, 2005, Karl was "irritable" and records that Karl was having problems with his hips on

that fits Dr. Frye's theory of the case more tightly is whether Karl suffered from neurodegeneration during this timeframe because Dr. Frye's theory is that the vaccines caused Karl to suffer neurodegeneration. Exhibit 16 at 1; exhibit 21 at 3.

Dr. Frye's testimony in this regard is inconsistent. Generally, Dr. Frye described Karl's regression as occurring over a long period, such as January to April or January to July, rather than immediately after the vaccination. See, e.g., Tr. 659:7-13 (agreeing that Karl's regression occurred "in a four to five-month period of time"). But he also testified on redirect that the timing of Karl's regression was within the medically accepted period of three weeks after vaccination. See Tr. 659:14 to 660:10; see also section IV.F.1.b (discussing Dr. Frye's implicit acceptance of the Edmonds paper).

In either case, Dr. Frye did not identify any medical records which show that Karl, in the last two weeks of January and first two weeks of February, stopped being able to do something he previously could do. Dr. Frye did, however, indicate that a review of Karl's medical records from before February 11, 2005 revealed that none of his caregivers noted spasticity during an examination. Tr. 647:25 to 648:4.

cross-crawl. Id. at 6. Even more important to Dr. Frye's opinion is the notation on February 11, 2005, that Karl was "spastic."⁸⁴ Id. A medical definition of "spastic" is "hypertonic, so that the muscles are stiff and the movement awkward." Dorland's at 1741.

Dr. Frye stated that spasticity differs from increased tone. Tr. 647:12-23, 707:12-14. Spasticity suggests that "the neurons in the motor cortex are severely damaged and are no longer controlling the neurons in the spinal cord. And with that time period to go from maybe some increased tone to becoming spastic suggests a very quick and fast regression." Tr. 648:9-14.

Dr. Snodgrass did not agree that the chiropractor's report of "spasticity" marked a regression in Karl. Tr. 788:23 to 789:8; see also Tr. 577:12-16. Dr. Snodgrass acknowledged that the chiropractor's records "often say spastic, stiff, et cetera." But, unlike Dr. Frye, Dr. Snodgrass saw the chiropractor as "reporting on the same general phenomenon which first became evident to Dr. McDonough in January." Tr. 336:26 to 337:4. In this context, Dr. Snodgrass stated that "I think he's [Dr. Frye has] missed the point that Karl was abnormal in the fall and by January he was showing new findings of increased tone. And that was an important marker, something significant had changed." Tr. 338:5-9.

⁸⁴ Dr. Frye defines "spasticity" as

an abnormality in the balance of the muscles of the limb such that the limb which the muscles affect[ed] are either limited in range of motion on either passive or dynamic exam. That is, you can have spasticity where you can have some contracture which limits your range of motion, or you could have a reactive spasticity[,] when you dynamically look at the muscle there is what we call a catch because one set of muscles has abnormal reaction to that movement.

Tr. 705:13-22. According to Dr. Frye, "hypertonia" is "not the same thing" as spasticity. "Hypertonia . . . is no limited range of motion, and . . . can be to a mild or severe extent. You can think of somebody with spasticity as being on the severe end of hypertonia." Although "spasticity is related to . . . the same process[,] it is a much more severe form of what we would say hypertonicity. . . . [I]f you say hypertonicity you're just talking about, you know, some tone in the limb without any limitations in movement of the limb." Tr. 706:6-19.

Dr. McDonough's medical records support a finding that Karl's motor function was worse in January 2005 than it was in December 2004. At the December 27, 2004 appointment, Dr. McDonough recorded that Karl has "normal muscle tone. There is no ankle clonus. Deep tendon reflexes appear to be symmetrical. He has good head control and fairly good truncal control but is not pulling himself to stand or crawling yet." For the December visit, Dr. McDonough assessed Karl with "possible mild gross motor delay." Exhibit 3 at 5-6.

On January 19, 2005, Dr. McDonough saw Karl again. The pediatrician's form shows that Karl's neuromuscular system was abnormal. The handwritten notation says "muscle tone [increased]" possibly in the upper and lower extremities. The note also seems to indicate that Karl was having two beats of clonus in his right ankle. Dr. McDonough determined that Karl had "gross motor delay" and referred him to physical therapy. Exhibit 3 at 3. The change from "possible mild gross motor delay" without a referral to therapy to "gross motor delay" with a referral to therapy constitutes a worsening from December to January.⁸⁵

The question becomes using January 19, 2005, as a point of comparison, do the chiropractor's records show that Karl was becoming worse in his gross motor functions? The first challenge in answering this question is that spasticity and increased tone are related concepts. According to Dr. Frye, "[y]ou can think of somebody with spasticity as being on the severe end of hypertonia. So . . . spasticity is related to . . . the same process but it is a much more severe form of

⁸⁵ The experts appear to accept that Karl worsened between December and January. Dr. Snodgrass, as quoted in the text above, stated that in January, Karl "was showing new findings of increased tone . . . something significant had changed." Tr. 338:5-9.

When Dr. Frye testified on redirect, he stated that Dr. McDonough's January 19, 2005 examination "found and suggested that there was some increase in tone in what looks like the lower extremities, and two beats of clonus on the right ankle." Tr. 640:16-19; accord Tr. 648:13-14 (Dr. Frye's testimony that before Karl saw the chiropractor, he had "maybe some increased tone"), 651:12-14 (Dr. Frye's testimony that in "January again he had this isolated gross motor delay and maybe a little bit of increased tone"). On cross-examination following his redirect testimony, Dr. Frye stated that on January 19, 2005, Dr. McDonough found "increased tone in Karl." Tr. 707:15-17.

what we [term] hypertonicity.” Tr. 706:11-16. Dr. Frye also stated that “changes in tone sometimes are very subtle things.” Tr. 647:13.

A second challenge is that the person observing and recording these “very subtle things” is a chiropractor. In Dr. Snodgrass’s opinion, a chiropractor has limited ability. Dr. Snodgrass stated:

I have trouble with, I agree with Dr. Frye that chiropractors do pay attention to motor function and muscle tone, and I think that a chiropractor would have some idea of what spastic means, but not necessarily the same that a physician would. And I think when you’re talking about a 13 or 14-month-old child, I don’t think chiropractors are in a position to make any nuanced statements about them. I think if they say he’s stiff or he’s less stiff as they said later, less rigid, I’d accept that. But I don’t believe they are trained to evaluate infants, and infants are tough to deal with.

Tr. 805:12-23.

A third challenge is that the chiropractor’s records show that the condition of Karl’s muscles fluctuated throughout February and March 2005. A selective summary of pertinent records is:

| Visit | Date | Note | ROM C/S | ROM L/S |
|-------|---------|--|---------|---------|
| 3 | 2/11/05 | Spastic | ↑ | |
| 5 | 2/16/05 | Less rigid – more comfortable on all 4’s | ↑ | |
| 6 | 2/18/05 | Less rigid – ‘happier’ | ↑ | |
| 7 | 2/20/05 | Stiff mid T ‘Happy moving around til last night’ | ↓ | |
| 9 | 2/24/05 | Spastic | ↑ | ↑ |
| 12 | 3/8/05 | Less hypertonicity. | ↑ | ↑ |

Exhibit 12 at 5-6.⁸⁶ Even if Karl’s chiropractor(s) (who remained unnamed) could skillfully detect “subtle changes in tone” in a 13-month-old boy, the resultant notes

⁸⁶ A check box with the heading “SPASM” is marked with a “T” or “T/L” in numerous entries, presumably noting the presence of spasm. The meaning of these (. . . continued)

are not consistent with Dr. Frye's opinion that after the vaccinations Karl "has devastating regression that continues until April." Tr. 657:16-17.

Dr. Frye did not make a persuasive case that Karl had any regression, let alone a "devastating regression," from January through mid-March 2005. Again, Dr. Snodgrass observed that the Palucks were not taking Karl to see a medical doctor in February. When the Palucks provided histories about Karl's development after his seizures began in July 2005, the Palucks generally told the doctors that Karl was not doing well in December 2004 (when he was 11 months old) and got worse in April 2005 (when he had an MRI). See, e.g., exhibit 11 at 5 (Children's Hospital narrative summary). Nonetheless, it is Dr. Frye's opinion that Karl was "worsening between January and March even though the parents may not have been seeing or perceiving that same worsening." Tr. 731:3-5.

The Palucks have not provided any evidence that they observed Karl worsening in February. The Palucks have also not provided any evidence to explain why, if Karl was as sick as they claim, they did not take him to a medical doctor in February. Previously, the evidence shows, when the Palucks thought that Karl was sick, such as November and December 2004, they brought him to the doctor's office. The Palucks brought Karl to Dr. McDonough's office for his one-year check-up. After the vaccination, the Palucks again took Karl for a possible ear infection on March 3, 2005. Exhibit 3 at 63.

While the March 3, 2005 visit was not to check on Karl's development, Ms. Paluck's encounter with Dr. Sherman gave Karl's mother an opportunity to note any new problems. Dr. Sherman's record does not memorialize any observations or discussions that Karl was in the process of experiencing anything like the "devastating regression" that Dr. Frye opined he was having between January and April. See exhibit 3 at 63.

Arguably, the chiropractor's entry for March 17, 2005, could represent a marked deterioration in Karl's functioning. On that date, the chiropractor recorded "palpation of spine painfull [sic] Baby cried loud when touched." Exhibit 12 at 7. Dr. Frye interpreted this note as "suggesting he's starting to have spasticity of some of the axial musculature and back pain." Tr. 650:1-3.

marks is not known for certain, but could be abbreviations for "thoracic" and "lumbar." See Medical Abbreviations (15th ed. 2011) at 184, 312.

This is only an arguable position because Karl's health cannot be assessed accurately with just one record. On March 27, 2005, Ms. Paluck informed Dr. Peterson at the Dickinson Clinic that Karl had experienced a runny nose for two weeks, and had a wheezy cough for four days. Exhibit 3 at 64. In addition, on March 27, 2005, Ms. Paluck told the chiropractor that Karl was ““Doing well ‘til yesterday’ [and] ‘took a few crawl steps.’” Exhibit 12 at 7. These entries create some uncertainty about whether Karl on March 17, 2005 was having an isolated bad day in the context of a common cold or was starting a more significant regression.

The experts continue the dispute over when Karl started having regression after the January 2005 vaccinations. Dr. Frye compared Dr. McDonough's April 13, 2005 and January 19, 2005 reports. In January, Dr. McDonough reported Karl as having “isolated gross motor delay and maybe a little increased tone,” whereas in April “he’s describing a very different child who has global developmental delay.” Tr. 651:12-14 and 19-20. Dr. Frye also noted that the April report recorded that Karl “has decreased hip flexion, something [Dr. McDonough] had not mention[ed] previously, [a development] suggesting that again he has spasticity, not just increased tone . . . , which is what the chiropractor had mentioned back [o]n . . . February 11th.” Tr. 652:11-17. With regard to Dr. McDonough’s neurologic examination, Dr. Frye stated

[Karl] has increased tone in his . . . upper and his lower extremities. [Dr. McDonough] also mentions that he is not speaking at this point. So on the 19th he was actually saying mama and dada, but now he’s not speaking at all. And he has obvious speech, fine, and gross motor developmental problems. So, before, where the Denver had actually showed us that he was normal in fine motor and language, now we’re seeing he has multiple developmental problems and he has lost all of his speech.

Tr. 653:6-15. According to Dr. Frye, the findings on April 13, 2005, “most definitely” suggest regression in Karl’s development. Tr. 653:16-18.

Dr. Snodgrass, however, disagreed that Karl’s health experienced a “precipitous decline with no improvement” between January and April 2005. Tr. 790: 3-7. Dr. Snodgrass gave several reasons for his opinion:

[T]he single most important thing is that we had a lot of calls and doctor visits in November and December. If Karl had a precipitous

decline in January and February, these parents who seem to be responsible parents would have been calling and visiting the doctor, that's number one. Number two, when they did visit Dr. Siriwan . . . in April they said that he had improved rather than that he had had a precipitous decline. I think Karl was going through cycles of getting a bit better and a bit worse going back in the fall, and those cycles of getting better and worse continued after the 1st of the year.

Tr. 790:9-21. When asked if the course of Karl's condition would have been different but for the vaccination – a question asked of Dr. Frye by the undersigned – Dr. Snodgrass stated that he saw “no evidence that the vaccines changed the course of his disorder.” Tr. 793:5-6. Dr. Snodgrass continued:

[A]s I have said[,] Karl was fluctuating getting better and getting worse in the fall, and then in January, February, and March. But his parents told Dr. Siriwan that he was actually better at the time they saw the doctor in April. I think his parents would be the single best judge of that. I think the amount of hip flexor abnormality that was present was probably greater in April than in January, but there was no ankle clonus. So in other words we have certain areas where he looked a bit worse than he did in January and others where he did not. And he was not speaking, Dr. McDonough said no words in January. Dr. Siriwan indicated no words. But he was babbling at least according to mother's phone call on March 22nd.

Tr. 793:9-23.

These disputes are largely academic. Even if Karl's March 17, 2005 visit to the chiropractor marked a turning point – a proposition for which there is a scintilla of support in the medical records – a worsening on this date would be approximately eight weeks after the January 19, 2005 vaccination. Since the bound of the appropriate temporal limit is three weeks, a March 17, 2005 worsening would be approximately five weeks too late.⁸⁷

For these reasons, the Palucks have not met their burden of presenting preponderant evidence that they are entitled to compensation. Karl's development

⁸⁷ If the appropriate temporal relationship were doubled from three weeks to six weeks, a worsening on March 17, 2005 would still be two weeks too late.

after the January 19, 2005 vaccinations did not fit Dr. Frye's prediction. This discrepancy undermines their attempts to establish Loving prongs five and six (corresponding to Althen prongs two and three). See Pafford, 451 F.3d at 1358 (Fed. Cir. 2006) ("If, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame.").

V. Factors Unrelated to the Vaccinations

Because the Palucks did not meet their burden of proof, the Secretary does not face the burden of establishing a factor unrelated to the vaccinations caused Karl's neurodegeneration. See Doe v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1358 (Fed. Cir. 2010) ("[petitioner] Doe never established a *prima facie* case, so the burden (and attendant restrictions on what 'factors unrelated' the government could argue) never shifted"). Nevertheless, the Secretary has identified various factors that caused or contributed to Karl's decline. One of these factors is Karl's mitochondrial disorder. The Secretary argues that "Dr. Frye himself has provided no reason to conclude logically that Karl's condition more likely than not resulted from immunizations as opposed to simply the progress[ion] of his mitochondrial dysfunction." Resp't Posthr'g Br., filed Feb. 18, 2011, at 65. Another set of factors can be classified as environmental stressors, including Karl's otitis media, erythema multiforme, and April 27, 2005 MRI. See id. at 62-64.

The parties paid relatively little attention to these potential alternative etiologies. Dr. Snodgrass offered some testimony, Tr. 294:24-295:14, 336:19-337:19, 374:5-21, 476:19-22, 483:2-25, 581:23-582:24, but the quantum of evidence was relatively small.

Because resolution of this topic would have no effect on the outcome and because any assessment would be based upon limited information, the undersigned chooses not to determine whether any of the factors unrelated to the vaccinations affected Karl. See Hibbard, 698 F.3d at 1364-65 (noting a special master may resolve only the issues necessary to determine whether the petitioners are entitled to compensation). These issues, however, would be relevant if the Palucks had met their burden of proof regarding all six Loving factors.

VI. Conclusion

The Court's Opinion and Order required an assessment of (1) whether the Palucks' case should be categorized as one seeking compensation for a new injury

or for a significant aggravation of a pre-existing condition and (2) the evidence pertinent to the appropriate test. On the first point, the evidence preponderates in favor of finding that Karl was showing neurologic problems before his vaccination. See section III. Thus, the Palucks' claim for post-vaccination neurodegeneration is a claim for significant aggravation.

On the second point, the evidence and arguments have been re-examined pursuant to the significant aggravation test set forth in Loving. As discussed in section IV, Dr. Frye's opinion was not as persuasive as Dr. Snodgrass's opinion. Although Dr. Frye asserted that Karl experienced a "devastating" neurologic regression through April 2005, Tr. 657:10-19, this view is not borne out by the evidence. Dr. Snodgrass's opinion about how Karl developed immediately after the vaccination more closely tracked the medical records. Karl's parents, who had previously taken Karl to his pediatrician for routine and non-routine illnesses, had a chiropractor treat Karl. At least for the first two months following vaccination, the chiropractor's records contain more indications that Karl was improving than notations that Karl was declining. Ultimately, the weight of the expert testimony does not support the Palucks' position. See Barnette v. Sec'y of Health & Human Servs., No. 06-868V, --- Fed. Cl. ---, 2013 WL 1384429, at *10 (2013) (concluding that the special master committed no reversible error "in choosing the interpretation of one qualified expert over another"); Lankford v. Sec'y of Health & Human Servs., 37 Fed. Cl. 723, 727 (1996) (affirming a special master who "confronted the task of choosing between two competing expert opinions by articulating a reasoned basis – drawn from the evidence – for preferring one over the other").

For reasons explained above,⁸⁸ the Palucks have not demonstrated that they are entitled to compensation. The Clerk's Office shall enter judgment in accord with this decision unless a motion for review is filed. The Clerk's Office is also instructed to provide a copy of this decision to the assigned judge pursuant to Vaccine Rule 28.1(a).

IT IS SO ORDERED.

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

⁸⁸ After the Court's Opinion and Order, the chief special master found Dr. Frye's opinion about how a vaccination can affect a mitochondrial disorder not persuasive. Bast v. Sec'y of Health & Human Servs., No. 01-565V, 2012 WL 6858040 (Fed. Cl. Spec. Mstr. Dec. 20, 2012), mot. for rev. filed (Jan. 22, 2013). The decision in Bast has not affected the outcome in the Palucks' case.