

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

CHRISTOPHER LOVING and CARLA *

LOVING, parents of Camille Loving, *

Petitioners, *

v. *

SECRETARY OF THE DEPARTMENT *

OF HEALTH AND HUMAN SERVICES, *

Respondent. *

No. 02-469V
Special Master Christian J. Moran

Filed: March 2, 2010

significant aggravation claim,
motion for reconsideration or
clarification, stipulation offered by
respondent during trial, findings of
fact

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

**PUBLISHED RULING ON MOTION FOR
RECONSIDERATION OR CLARIFICATION***

Christopher Loving and Carla Loving claim that a diphtheria, tetanus and acellular pertussis (“DTaP”) vaccine significantly aggravated a neurological problem, known as infantile spasms, suffered by their daughter, Camille Loving. Before Camille received the third dose of the DTaP vaccine on March 27, 2001, she had already experienced infantile spasms. Within minutes after this third dose of the vaccine, Camille had a seizure. Afterwards, she started

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

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

experiencing infantile spasms more frequently. The Lovings claim that the third DTaP vaccination caused the worsening of her problems, and, pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 et seq. (2006), the Lovings seek compensation for this worsening.

On July 30, 2009, the undersigned issued a ruling regarding the Lovings' claim for entitlement. Concisely summarized, the undersigned found that the DTaP vaccine worsened Camille's infantile spasms for some unspecified period of time but that this worsening did not affect Camille's long-term development because devastating problems in Camille's development were more probable than not once developed infantile spasms. Loving v. Sec'y of Health & Human Servs., No. 02-469, 2009 WL 3094883 (July 30, 2009). The July 30, 2009 ruling discussed a stipulation made by respondent during the hearing. Ruling, slip op. at 31, 2009 WL 3094883, at *27.

The Lovings seek reconsideration or clarification of the July 30, 2009 ruling in two respects. First, the Lovings argue that the undersigned did not interpret correctly a stipulation offered by respondent. Second, the Lovings also argue that the undersigned made statements that do not conform fully with certain statements made by the Honorable Charles F. Lettow in his initial review of the undersigned's decision on entitlement.

For the reasons discussed below, the Lovings' first argument is not persuasive. Their proposed interpretation of respondent's stipulation does not match what respondent actually intended. Thus, the motion for reconsideration regarding the stipulation is DENIED. The Lovings' second point is valid. Due to imprecise language in the July 30, 2009 ruling, the undersigned GRANTS the motion for clarification and revises the July 30, 2009 ruling. Additional relief, however, is not warranted.

I. Facts and Procedural History

Previous decisions by Judge Lettow and the undersigned set forth the facts about Camille's medical history. A synopsis of these facts is that Camille was born on August 2, 2000. In January 2001, Camille began having infantile spasms, which is a generalized form of epilepsy. Children having infantile spasms "often are developmentally challenged." Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 137 (2009).

Doctors treated Camille for infantile spasms. While on medication, Camille's condition improved. The scope and permanence of this improvement were disputed by the experts who testified in this case.

On March 27, 2001, Camille received a third dose of the DTaP vaccine. Within minutes of this vaccination, Camille had a seizure. Thereafter, Camille continued to have seizures that the doctors could not control. By the time of the hearing when Camille was seven years old, Camille's mental development resembled the development of a three-year-old child.

The Lovings filed their petition on May 9, 2002. They filed an expert report from Dr. Robert M. Shuman on December 23, 2005, and a supplemental report from him on January 18, 2006.

Respondent responded to the petitioners' submissions by filing a report, pursuant to Vaccine Rule 4, that maintained that the Lovings were not entitled to compensation. Respondent also presented the report of Dr. Michael Kohrman as exhibit A. Dr. Kohrman stated that "There is no evidence . . . that the natural course of [Camille's] infantile spasms was in any way changed by vaccination." Exhibit A at 5. Dr. Kohrman's report was the basis for respondent's assertion that "Camille's pattern of seizures was part of the natural course of her infantile spasms, that was not changed in any way by the vaccination." Resp't Rep't at 9. Respondent filed articles on which Dr. Kohrman relied, including at least two articles describing the long-term outcome for children who are afflicted with infantile spasms. These articles, exhibit E (M.T. Mackay et al., Practice Parameter: Medical Treatment of Infantile Spasms: Report of the American Academy of Neurology and Child Neurology Society, 62 Neurology 1668 (2004) and exhibit K (T. Baram, Myoclonus, Myoclonic Seizures, and Infantile Spasms, 1 Pediatric Neurology: Principles & Practice 1065 (2006)), were discussed during the hearing.

The Lovings filed articles on which Dr. Shuman relied. In advance of a scheduled hearing, the Lovings filed a supplemental report from Dr. Shuman (exhibit 90) explaining the significance of the articles. On November 8, 2006, the Lovings filed additional medical articles (exhibits 91-95). On November 16, 2006, the day before the hearing, the Lovings filed additional medical records, including records from Dr. Shuman (exhibits 96-100).

The first day of the hearing was November 17, 2006. At the beginning of the hearing, the following exchange occurred:

MR. DOBREFF [counsel for the Lovings]: Right. Actually the critical issue is, is were these significant worsening of events afterwards an actual result of the course of the disease or were they caused, was the substantial worsening caused by the vaccine.

MR. RABY [counsel for respondent]: I think that's a fair statement of the issues.

Tr. 7:20-25.

Shortly before the lunch recess on the first day of the hearing, counsel for respondent requested a sidebar conference, which was not recorded. The undersigned recalls that the purpose of this sidebar conference was to determine whether Dr. Shuman was going to testify about exhibits 91-100, which were filed just before the hearing. Following this unrecorded sidebar conference, the following discussion took place:

MR. RABY: I spoke with Dr. Kohrman about what we believe the evidence will show and Dr. Kohrman agrees that the, that whatever is responsible for Petitioner's seizure activity, is also responsible for her delayed development.

And so for instance, if this Court were to find that the, that there was a change in her condition, and that change in her condition was responsible for her increased seizures, then we wouldn't contest that her lack of development was a sequella of that –

MR. DOBREFF: Change in seizures.

MR. RABY: -- worsening.

MR. DOBREFF: Or the change, worsening conditions --

MR. RABY: So is that fair to say?

MR. DOBREFF: Thank you, your Honor.

MR. RABY: I hope that moves us forward.

MR. DOBREFF: I just, so understand it, that I'm not by this stipulation, I'm not being required to tie in the change in developmental, or in the developmental delay to the change in seizures. By the stipulation, I'm skipping that step. And the real question just is, did the vaccine cause a change in the seizure condition.

THE WITNESS: Yes.^[1]

MR. DOBREFF: That will allow me to focus my examining, thank you, your Honor.

Tr. 137:22-138:23. The pending motion for reconsideration is directed to the correct interpretation of these remarks, which the parties term a stipulation.

The hearing on November 17, 2006, did not conclude the presentation of evidence. Two additional days of testimony (November 26-27, 2007) were necessary. Additional details about the scope of the hearing are set forth in section II.B. below.

Following the conclusion of the hearing and the submission of briefs, the undersigned found that the Lovings were not entitled to compensation. The undersigned found that the Lovings had failed to demonstrate one element required for compensation – that Camille's seizure after vaccination occurred within a time appropriate to infer that the DTaP vaccine aggravated Camille's infantile spasms. Decision, 2008 WL 4692376, at *10 (Oct. 6, 2008).

¹ The transcript identifies this speaker as "the witness." The Lovings' brief asserts that the speaker was "respondent's expert." Pet'r Mem. at 3.

The Lovings filed a motion for review, which was assigned to Judge Lettow. Judge Lettow vacated the October 6, 2008 decision and remanded for additional adjudication by the undersigned. Loving, 86 Fed. Cl. 135.

After Judge Lettow's ruling, the undersigned established a briefing schedule and instructed the respondent to address the stipulation. Respondent's brief quoted a portion of the transcript, which is set forth above. Respondent then asserted that:

These statements taken together indicate that the stipulation made by the parties was that whatever is responsible for the seizures that Camille experienced beginning on March 27, 2001, is also responsible for Camille's developmental delay. That is: if the court finds that petitioners put on sufficient evidence to show that the March 27, 2001, seizure represents the onset of a significant aggravation of Camille's condition, petitioners do not have to put on additional evidence to show that Camille's current developmental delay was the result of the significant aggravation. As counsel for petitioners stated at the hearing, the purpose of the stipulation was to allow petitioners' counsel to focus his examination of petitioners' expert.

Resp't Resp. to Order on Remand, filed April 17, 2002, at 8-9. This statement provides little, if any, additional insights about the meaning of the stipulation because respondent's brief essentially repeated the what had been stated during the hearing.

The undersigned responded to the order from Judge Lettow in a ruling, filed July 30, 2009. This ruling found that Camille's infantile spasms were worse after the March 27, 2001 DTaP vaccination. However, this ruling also found that respondent had met her burden of establishing, by a preponderance of the evidence, that "Camille's current condition is predominantly due to the infantile spasms, which began in January 2001, and not due to the resumption of her infantile spasms following her third DTaP vaccination on March 27, 2001. A preponderance of the evidence supports a finding that there is relatively small difference, if any, between Camille as she actually developed and the hypothetical Camille as she would have developed but for receiving the third dose of the DTaP vaccination." Ruling, slip op. at 31, 2009 WL 3094883, at *24.

The undersigned found that the existing record was not sufficient to determine whether the Lovings were entitled to any compensation because the parties had not considered whether a disease can be worsened temporarily, but without any permanent consequences. In doing so, the undersigned also commented that the ruling complied with the stipulation. The July 30, 2009 ruling quoted the first sentence of the stipulation: "whatever is responsible for [Camille's] seizure activity, is also responsible for her delayed development." Ruling, slip op. at 35, 2009 WL 3094883, at *27, quoting tr. 137-38. The ruling did not quote the second sentence of

respondent's stipulation – “if this Court were to find that the, that there was a change in her condition, and that change in her condition was responsible for her increased seizures, then we wouldn't contest that her lack of development was a sequella of that [worsening].” In conjunction with the July 30, 2009 ruling, the undersigned scheduled a status conference to discuss additional proceedings in this case.

In the status conference, the Lovings argued that the July 30, 2009 ruling failed to enforce the stipulation made by the respondent. The undersigned agreed that reconsideration was appropriate and set a schedule for submitting briefs. Order, filed Sept. 21, 2009. The Lovings filed their motion for reconsideration or clarification with a supporting memorandum. This ruling refers to the Lovings' motion as “Pet'r Mot.” and the associated brief as “Pet'r Mem.” The respondent filed an opposition. The Lovings did not file a reply. Thus, the Lovings' motion for reconsideration or clarification is ready for adjudication.

II. Analysis

A. Standards for Reconsidering and Clarifying Decisions

“A court may grant such a motion when the movant shows ‘(1) that an intervening change in the controlling law has occurred; (2) that previously unavailable evidence is now available; or (3) that the motion is necessary to prevent manifest injustice.’” System Fuels, Inc. v. United States, 79 Fed. Cl. 182, 184 (2007), quoting Amber Resources Co. v. United States, 78 Fed. Cl. 508, 514 (2007).

Trial courts have discretion to review their own interlocutory decisions that have not been subject to an appeal. Exxon Corp. v. United States, 931 F.2d 874, 877 (Fed. Cir. 1991); see also AshBritt, Inc. v. United States, 87 Fed. Cl. 654 (2009) (granting motion for clarification).

As mentioned earlier, the Lovings' motion for reconsideration or clarification raises two different issues. First, the Lovings argue that the July 30, 2009 ruling failed to effectuate respondent's stipulation. Pet'r Mem. at 1-11. Second, the Lovings contend that the July 30, 2009 ruling conflicts with findings made by Judge Lettow in his opinion and order. Pet'r Mem. at 12-16.

Preliminarily, the undersigned finds that the Lovings have made a sufficient showing that reconsidering the July 30, 2009 ruling is appropriate to “prevent manifest injustice.” The Lovings' showing is particularly strong for their first argument, pertaining to the stipulation. If the Lovings were correct, then the process for determining damages would be streamlined. If the undersigned actually misinterpreted the stipulation, requiring an extensive evidentiary proceeding would be inefficient, if not “unjust.” For their second argument, the Lovings' argument seems to request clarification, rather than reconsideration.

B. Enforcement of Stipulation

The first issue presented in the Lovings' motion for reconsideration is whether the undersigned correctly interpreted the respondent's stipulation. In their briefs, the parties offer different interpretations of the stipulation.

Petitioners argue that the undersigned did not enforce respondent's stipulation when the undersigned found that Camille's pre-existing infantile spasms were primarily the cause of her developmental delays. Pet'r Mot. at 1 ¶ 2. Petitioners argue that respondent's stipulation was that if petitioners proved that Camille's pre-existing seizure disorder was aggravated by the March 27, 2001 DTaP vaccination, then respondent would not contest that Camille's developmental delay was a sequella of the aggravation of the seizure disorder. Thus, petitioners argue that they were not required to prove specifically that Camille's developmental delay was a result of the change in her seizure activity. Pet'r Mot. at 1-2 ¶¶ 6,8. Petitioners further argue that because the undersigned found that the March 27, 2001 DTaP vaccination significantly aggravated Camille's pre-existing seizure disorder, a conflict was created when the undersigned's later found that Camille's pre-existing seizure disorder was the primary cause of her development delay. Pet'r Mem. at 16.

Respondent contends that "with the benefit of hindsight and in light of petitioners' current representations, it seems apparent that there was never a meeting of the minds as to what the statements now in question meant." Respondent also argues that terms such as "seizure disorder," "seizure activity," "seizures," and Camille's "condition" were not defined with sufficient clarity to explain what respondent meant. Resp't Br., filed Oct. 27, 2009, at 8.

In interpreting a stipulation, "[t]he primary rule is to ascertain the intent of the parties." Stafford v. Crane, 382 F.3d 1175, 1180 (10th Cir. 2004). In circumstances in which the parties' intention is reflected in the terms of a stipulation, a court should usually not relieve a party of a stipulation. Miller v. Eby Realty Group LLC, 396 F.3d 1105, 1116 (10th Cir. 2005); Stafford, 382 F.3d at 1180.

The undersigned holds the firm conviction that the meaning offered by the Lovings of the respondent's statement was not the intent of respondent's counsel when he spoke during the November 17, 2006 hearing. The undersigned participated in the sidebar conference requested by respondent's counsel just before the stipulation was offered. The undersigned did not comprehend then that respondent's counsel was agreeing that a worsening of the infantile spasms caused Camille's developmental delay. See Syntex Ophthalmics, Inc. v. Novicky, 795 F.2d 983, 986 (Fed. Cir. 1986) (noting that trial judge witnessed how the stipulation was entered).

A finding that respondent intended to stipulate that the worsening of the infantile spasms caused Camille's developmental delay would be inconsistent with the position taken by respondent both before the hearing and during the hearing. Before the hearing, Dr. Kohrman opined that "There is no evidence . . . that the natural course of [Camille's] infantile spasms was

in anyway changed by vaccination.” Exhibit A at 5. The reference to “natural course” indicates that respondent believed that Camille’s ultimate outcome was determined by her initial onset of infantile spasms in January 2001. See Resp’t Rep’t at 9. This belief is not consistent with a statement that the worsening after the March 27, 2001 DTaP vaccination caused Camille’s developmental delay.

The actions of respondent’s counsel during the first day of the hearing are also consistent with an understanding that Camille’s prognosis and the natural course of infantile spasms were relevant. Respondent’s counsel cross-examined Dr. Shuman and attempted to gain a concession from Dr. Shuman that a child like Camille could have had more seizures even if the child was not vaccinated. Tr. 231:3-232:15.² The Lovings’ counsel did not object to these questions as inconsistent with the stipulation.

Further, on the first day of the hearing, respondent’s counsel asked Dr. Kohrman some questions about how children with infantile spasms typically develop. Dr. Kohrman stated that of the children with infantile spasms “90 percent of these children will be developmentally disabled. . . . That means only 10 percent of them are normal.” Tr. 244:20-22. Dr. Kohrman also discussed the practice parameter describing outcomes for children with infantile spasms in the context of explaining the expected development of children with infantile spasms. Tr. 244:7-248:18. Again, the Lovings’ counsel did not object to this testimony as irrelevant due to the stipulation. The lack of an objection is important because if the Lovings had argued that the stipulation removed this issue from the case, then respondent’s counsel could have clarified his earlier statement.

The topics about which the Lovings’ counsel asked Dr. Shuman suggest that their counsel also understood that respondent’s stipulation did not eliminate the issue of Camille’s long-term development. For example, petitioners’ counsel elicited testimony from Dr. Shuman about the natural course of infantile spasms. The following exchange occurred among petitioners’ counsel, Dr. Shuman and the undersigned.

Q And Doctor, do you have opinion to reasonable degree of medical certainty, based on the fact that the infantile spasms were controlled in review of the records and the EEG's up through this time. That the prognosis for this

² Dr. Shuman parried this line of questioning by saying that although resumption of seizures in the absence of a provoking agent was “possible,” it was not likely. Dr. Shuman’s response is not relevant for determining the parties’ intention in the stipulation. The important point is that respondent’s counsel asked how a child with infantile spasms but without a vaccination would have fared. If respondent’s counsel intended to stipulate away the issue of Camille’s development, then questions about how other children with infantile spasms developed would not have been relevant.

child in terms of the seizure disorder at that time, would be good?

A The prognosis for the seizure disorder at this point in time, with absence of clinical seizures and with the EEG still abnormal, is far, far, far, far, far better than it was on January 26th. This is a marked improvement. She is not so good that she can withstand the potential epileptogenesis of the DPT vaccine.

Q Without provocation, would her prognosis for keeping the seizures controlled be good at that point in time, sir?

A It's pretty good. The data are really silent on how such children respond with what degree of frequency to provocations. But if you get a child to this point, then the suggestion is that you've got a 70 or 80 percent chance of getting rid of everything.

SPECIAL MASTER MORAN: If you can --

THE WITNESS: A child with infantile spasms.

SPECIAL MASTER MORAN: If you could answer the, my question to some degree of probability as opposed to speculating. You have answered, but it would just be speculation, if you could just say that. As of March 6th, do you think that Camille was likely to become better or was she likely to become normal? We talked before about the range of the outcome, saying that there are some people who improve and there are some people who improve to normal.

THE WITNESS: She was going to become better. I can't tell if she was going to become normal.

SPECIAL MASTER MORAN: Okay.

THE WITNESS: I'm secure that she was going to become better.

SPECIAL MASTER MORAN: And then what would, and when you say that she'd become better, do you think that she'd be

able to attend school? You know, we talked about sometimes that people –

THE WITNESS: Yes.

SPECIAL MASTER MORAN: -- aid. Who have full time aid, do you think that she'd be able to walk unassisted?

THE WITNESS: The ability, I'm sort of begging the question. The ability to forecast a child's development at seven months of age is very poor. A normal child still has a measurable incidence of school failure, if you look at them at six months of age. And try to prognosticate. Given a child who's been damaged with infantile spasms, I know that their risk of failing to meet normal is much greater than the normal population. I can only assure you that she was going to be better. I can with reasonable, with reasonable certainty say that she would have been functional. I think the old legal 51 percent security. I think it's more probable than not, that she would have been in school in the 80, 85 IQ area. I don't think she'd have been in a wheelchair, I don't think she'd have had to be fed, I don't think she would have been dependent upon an aid. I think she would have been --.

SPECIAL MASTER MORAN: You can see why I asked my question, saying if you can answer it with a degree of certainty or refrain from speculating. As I realize that there is –

THE WITNESS: Yes.

SPECIAL MASTER MORAN: -- so much speculation inherent in –

THE WITNESS: That's speculation. Yes. Best guess.

SPECIAL MASTER MORAN: Go ahead, Mr. Dobreff.

BY MR. DOBREFF:

Q Doctor, in terms of your opinions that you just stated, are you saying that it was more probable than not that the opinion that you offered was more probable than not?

A Yes.

Q Doctor, in terms of the seizures, is it your, do you have an opinion to a reasonable degree of medical certainty that without provocation of the pertussis vaccine, the seizures in this child would have remained controlled?

A My clinical experience says they would have remained controlled.

Tr. 165:7-168:15. In this passage, petitioners' counsel asked Dr. Shuman what Camille's "prognosis" was before she received the third DTaP vaccination. These questions are consistent with an understanding that the petitioners were required to introduce some evidence about how Camille would have developed without the "provocation" – to quote petitioners' counsel – of another DTaP vaccination. The undersigned's questions attempted to learn additional details about Camille's prognosis – what activities Camille would have been capable of doing if she had not received the third DTaP vaccination. Finally, the petitioners' counsel confirmed that Dr. Shuman's statements were expressed with a reasonable degree of probability.

This exchange occurred after the lunch recess during the November 17, 2006 hearing. It also happened after respondent's counsel made the statements that are the subject of the Lovings' motion for reconsideration. These questions about Camille's prognosis suggest that the petitioners' counsel and the undersigned understood that even after respondent's statement, how Camille would have developed but for the third DTaP vaccination was a contested issue.

After the first day of the hearing, the hearing did not resume for approximately one year to allow the experts to file additional reports and material. When the hearing resumed, the attorneys continued to elicit information about the natural course of infantile spasms. How both parties conducted the second and third days of the hearing reinforces the finding that the parties did not intend to stipulate that Camille's worsening (as opposed to the pre-existing infantile spasms) caused her developmental delay. The Lovings' proposed interpretation of the remarks by respondent's attorney suggests that a controlling issue in this case was simply whether Camille worsened. If so, the evidentiary presentations would have been comparatively easy. The Lovings summarized the information showing that Camille worsened in a six-line chart. See Pet'r Mem. at 15-16.

In point of fact, much of the parties' evidence was devoted to discussing the long-term outcomes of children with infantile spasms. Tellingly, at the start of the second day of the hearing, the Lovings asked Dr. Shuman about the practice parameter, an article that showed that some children with infantile spasms improved. See tr. 286:24-292:25, discussing exhibit E (M.T. Mackay et al., Practice Parameter: Medical Treatment of Infantile Spasms: Report of the American Academy of Neurology and Child Neurology Society, 62 Neurology 1668 (2004)). Beginning the second day of the hearing with testimony about the degree to which children with infantile spasms improved suggests that petitioners' counsel believed that this topic was an important issue. If the amount of expected improvement were not relevant to determining whether the Lovings were entitled to compensation, the Lovings either could have ignored the topic entirely or could have presented this information in a place less conspicuous than as the lead-off topic.

The Lovings solicited testimony from Dr. Shuman about the range of outcomes for children with infantile spasms at other points during the second and third day of the hearing. Tr. 305:17-306:12 (discussing exhibit E (the practice parameter) again); tr. 511:3-512:24 (discussing exhibit E on redirect); tr. 515:9-517:13 (discussing exhibit E and exhibit K). A thrust of Dr. Shuman's testimony is that because some children with infantile spasms improve, it is likely that Camille would have improved. The Lovings also cross-examined Dr. Kohrman about how children with infantile spasms develop. Tr. 630:2-635:14 (discussing exhibit E); tr. 638:14-639:3 (discussing which children have a better prognosis); tr. 642:25-645:9 (discussing exhibit E). If the Lovings believed that respondent's stipulation addressed Camille's current development, then this testimony was not relevant.

Similarly, respondent presented evidence about the long-term effects of infantile spasms. Respondent cross-examined Dr. Shuman about this point. Tr. 492:7-496:4. Respondent also questioned Dr. Kohrman about this topic. Tr. 531:24-533:11 (discussing exhibit K); tr. 548:5-552:7 (discussing exhibit E). All this testimony about the practice parameter, which presents data about how children with infantile spasms progressed, is relevant to whether Camille would have progressed.

The parties' briefs after the hearing discuss how Camille would have developed if she did not receive the third DTaP vaccination. Pet'r Br., filed Feb. 1, 2008, at 23-24, 30-31 ("prognosis prior to the DTaP"), at 51-52 (discussing exhibit K), at 69-70; Resp't Br., filed May 20, 2008, at 26-30; Pet'r Reply, filed June 23, 2008, at 43-49 (discussing Camille's "prognosis without the DTaP"); but see Pet'r Br. at 36 (quoting stipulation without analysis of its meaning). Again, if how Camille would have developed if she had not received the third DTaP vaccination had been resolved by respondent's stipulation, then the parties would not have argued how Camille would have matured. The extensive argument from both parties strongly suggests that the parties did not understand the stipulation to have resolved this issue.

In sum, the parties' actions during the hearing and after the hearing are consistent with an understanding that a dispute existed as to how Camille's pre-existing infantile spasms affected

her long-term development. These actions are strong evidence that the parties did not understand that the stipulation eliminated consideration of what Camille's natural course of infantile spasms would have been but for the March 27, 2001 DTaP vaccination. See Metropolitan Area Transit, Inc. v. Nicholson, 463 F.3d 1256, 1260 (Fed. Cir. 2006); Julius Goldman's Egg City v. United States, 697 F.2d 1051, 1058 (Fed. Cir. 1983); Dalles Irrigation Dist. v. United States, 82 Fed. Cl. 346, 356 (2008) ("the post-adoption actions of parties to a contract can be useful in guiding interpretation.").

For these reasons, the undersigned finds that the intent of the respondent was not to remove from the case the issue of Camille's long-term development. See Washington Hospital v. White, 889 F.2d 1294 (3d Cir. 1989) (remanding case to the trial court to make findings of fact regarding the parties' intent as part of the process for interpreting a stipulation).

The Lovings' argument to the contrary is mistaken. The Lovings argue that "In Camille's case, the pivotal issue was did the DTaP cause the significant aggravation of the seizure disorder beginning on March 27, 2001. Petitioner won that issue and is no longer required to prove the developmental delay was caused by the significant aggravation." Pet'r Mem. at 5. This argument is based upon a lack of precision in the meaning of words and phrases such as "change in her condition" and "significant aggravation."

The phrase "change in her condition" means that two conditions must be compared to determine whether there is a "change." However, the stipulation does not specify which conditions should be compared. There seems to be at least three different possible comparisons. First, one could compare Camille on March 26, 2001 (one day before she received the third dose of the DTaP vaccine) to Camille on March 29, 2001 (two days after the vaccination). This appears to be the Lovings' position. Second, the "change in her condition" could indicate a comparison between Camille as she actually existed on March 29, 2001 (two days after the vaccination), and a hypothetical Camille, who did not receive the vaccination, on March 29, 2001. Neither party seems to put forth this position. Third, the two conditions being compared could be Camille as she actually existed in 2007, and a hypothetical Camille as she would have developed but without receiving the March 27, 2001 vaccination. This seems to be respondent's position, at least before the hearing.

In seeking reconsideration, the Lovings seem to favor the first comparison – comparing the real Camille just before the March 27, 2001 vaccination with Camille just after vaccination. See Pet'r Mem. at 15-16 (presenting chart). This comparison is not the basis for respondent's stipulation. One of respondent's arguments for why the Lovings are not entitled to compensation is that Camille would have arrived at the same developmentally disabled condition, regardless of whether she received the DTaP vaccination because her pre-existing infantile spasms is such a devastating disease. See Resp't Rep't at 9 (stating "Camille's pattern of seizures was part of the

natural course of her infantile spasms that was not changed in any way by the vaccination.”)³ Throughout the hearing, respondent maintained the position that the vaccination did not alter the natural course of the infantile spasms and prefaced the language at issue in this motion by stating “whatever is responsible for Petitioner’s seizure activity, is also responsible for her delayed development.” Tr. 137. Consistent with this position, respondent presented extensive evidence showing that the natural course of infantile spasms leaves afflicted children disabled. Tr. 244-45, accord tr. 248 (testimony of Dr. Kohrman), 264 (same), 457-60 (cross-examination of Dr. Shuman), 547-552 (testimony of Dr. Kohrma); exhibit E at 1671, exhibit K at 1065. Respondent’s introduction of this evidence and the Lovings’ attempt to counter this evidence, see tr. 166-68 (testimony of Dr. Shuman), 286-93 (testimony of Dr. Shuman); suggest that the parties understood that the “change” to which respondent had referred was not just a comparison between Camille before the March 27, 2001 vaccination and Camille shortly after that vaccination. The parties understood that the natural course of the infantile spasms remained an issue in the case.⁴

Further, even if the respondent’s statement were interpreted as proposed by the Lovings, the outcome of the undersigned’s July 30, 2009 ruling would not differ. Respondent stated that “if this Court were to find that . . . there was a change in her condition, and that change in her condition was responsible for her increased seizures, then we wouldn’t contest that her lack of development was a sequella of that [worsening].” Tr. 137-38 (all emphasis added). Thus, to gain the benefit of respondent’s stipulation, the Lovings would be required to establish two predicates: (1) Camille’s condition changed, and (2) the change caused increased seizures. Even if the Lovings were correct that “there was a change in her condition” meant that Camille’s condition changed between March 26, 2001 and March 29, 2001, the Lovings would still be required to show that the “change in her condition was responsible for her increased seizures.”

Whether the number of seizures that Camille experienced “increased” depends upon the point of comparison. As discussed above, a primary topic during the evidentiary hearing was

³ Respondent also challenged the reliability of Dr. Shuman’s theory that DTaP vaccine can cause neurologic damage. Resp’t Br., filed May 20, 2008, at 32-33. Judge Lettow found that the Lovings met their burden of establishing causation. Loving, 86 Fed. Cl. at 149.

⁴ The factual circumstances in which this stipulation was developed make applying the contra proferentem doctrine not appropriate. This canon for interpreting legal documents states that ambiguities should be resolved against the party drafting the document. See Blue & Gold Fleet, L.P. v. United States, 492 F.3d 1308, 1313 (Fed. Cir. 2007), quoting E.L. Hamm & Assocs. Inc. v. England, 379 F.3d 1334, 1342 (Fed. Cir. 2004). Here, respondent did not “draft” any document. Instead, respondent’s counsel made an oral representation after less than ten minutes of discussion. The standards governing interpretation of writings should not always govern the interpretation of oral statements because writings are presumably made with more care, deliberateness and precision than oral statements.

how children with infantile spasms usually develop over time. Thus, a comparison involving Camille's long-term development is consistent with the parties' evidentiary presentations.

When the point of comparison is Camille as she actually developed and Camille as she would have developed but-for the vaccination, the Lovings have not established that Camille's total number of seizures increased. A hypothetical and simplified example helps to explain this point: with the vaccine, Camille experienced four seizures in April and four seizures in May. Without the vaccine, the hypothetical Camille would have experienced two seizures in April and six seizures in May. In this model, the number of seizures did not "increase." With or without the vaccination, Camille would have had eight seizures. Consequently, the Lovings have yet to fulfill the second premise for respondent's stipulation.⁵

Finally, not interpreting the stipulation as the Lovings have requested causes the Lovings little prejudice. The July 30, 2009 ruling explicitly permits the Lovings to present evidence about how Camille's actual condition differed from the condition in which she would have been if she did not receive the DTaP vaccination on March 27, 2001. Ruling, slip op. at 35, 2009 WL 3094883, at *27. Thus, the Lovings are in effectively the same position as if the respondent's counsel had not made any remarks, which could be understood as a stipulation, at all.⁶

For these reasons, the Lovings' motion to reconsider how the undersigned interpreted statements made by the respondent's counsel is DENIED. The Lovings have not established that the parties intended to resolve, by stipulation, the issue of how Camille would have developed but for the third DTaP vaccination.

C. Findings of Fact

The second argument raised in the Lovings' motion for reconsideration or clarification is that the undersigned's July 30, 2009 ruling included findings of fact in conflict with Judge Lettow's March 4, 2009 opinion. Pet'r Mot. ¶ 22-24; Pet'r Mem. at 12-14. The Lovings dispute a statement by the undersigned that Camille experienced more than one "clinical seizure" from January 30, 2001 through March 26, 2001. The Lovings' argument is valid because the July 30,

⁵ If different comparisons were made, then there would be a basis for finding that the number of seizures increased. For example, Camille experienced more seizures in the days following the March 27, 2001 vaccination than she experienced in the days preceding it. Camille also did experience seizures more frequently following the March 27, 2001 vaccination than she would have without the vaccination. Ruling, slip op. at 24, 2009 WL 3094883, at *8. These points of comparisons are not as useful because they do not involve Camille's long-term development.

⁶ The only prejudice to the Lovings is that their case is taking longer time to adjudicate, but this delay must be placed in context of the length of time that the Lovings required to obtain expert reports.

2009 ruling used imprecise language. Thus, revision of the July 30, 2009 ruling is appropriate. However, the change in wording does not require a change in the outcome.

The Lovings' argument is based, in part, upon the different roles played by judges of the Court of Federal Claims and special masters. Special masters are required to issue decisions, including "findings of fact." 42 U.S.C. § 300aa-12(d)(3)(A)(I). Judges of the Court of Federal Claims, in turn, review decisions of special masters. Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 869 (Fed. Cir. 1992). Judges may "set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. § 300aa-12(e)(2)(B) (quoted in Loving, 86 Fed. Cl. at 141). Findings of judges of the Court of Federal Claims are binding on special master when the case is remanded from a judge to a special master. Hanlon v. Sec'y of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998), aff'd 191 F.3d 1344 (Fed. Cir. 1999). The Lovings contend that the undersigned did not comply with this rule when making findings of fact in the July 30, 2009 ruling.

Judge Lettow's opinion and order states, under the heading "BACKGROUND AND PROCEDURAL HISTORY," that "Camille proved to be responsive to Sabril, and with that medication her seizures markedly decreased to the point where Camille had not had clinical seizures for a period of 56 consecutive days. Tr. 36:21 to 38:13." Loving, 86 Fed. Cl. at 137. Judge Lettow's opinion also quotes approximately one page of Dr. Kohrman's testimony on cross-examination in which Dr. Kohrman states that the video EEG showed Camille having one seizure. Id. at n.4. The Lovings assert that "Judge Lettow's factual finding was that Camille had one clinical seizure in 56 days prior to the DTaP." Pet'r Mem. at 12.

A seizure is defined as a single episode of epilepsy. Dorland's Illustrated Medical Dictionary (30th ed. 2003) at 1676. Epilepsy, in turn, is a "paroxysmal disturbance in brain function." Dorland's at 628; accord tr. 17:5-21. So, a seizure is generally a disruption in brain function. A "clinical seizure" is one type of seizure. A clinical seizure requires a doctor to observe the body's movements and to have it recorded on a EEG. Tr. 600:5-16; see also Dorland's at 376 (defining "clinical" as "pertaining to a clinic or to the bedside; pertaining to or founded on actual observation and treatment of patients, as distinguished from theoretical or basic sciences."). Based upon this definition of "clinical seizure," a person could have a "seizure" that is not a "clinical seizure" in that sense that the person had a disturbance in brain function that was not observed or recorded on an EEG.

The undersigned's July 30, 2009 ruling was not precise in describing Camille's seizure activity between January 30, 2001 and March 27, 2001. In pertinent part, the July 30, 2009 ruling states:

By March 26, 2001, 56 days had elapsed since Camille last had a clinical seizure that was observed. Tr. 458.⁷ The previous sentence contains two important qualifications. First, it discusses only clinical seizures. The March 6, 2001 EEG shows that Camille experienced one seizure within her brain that had a clinical manifestation. Tr. 462-63, tr. 530, tr. 535, tr. 547. Second, any discussion about the number of clinical seizures depends, in part, on the degree of observation.

Ruling, slip op. at 9, 2009 WL 3094883, at *7. Later, the undersigned stated that “it is more likely than not that Camille experienced clinical seizures between January 30, 2001 and March 26, 2001.” Ruling, slip op. at 26 n.22, 2009 WL 3094883, at *27. The phrase “clinical seizures” (plural) in this sentence is not accurate. Camille’s doctors confirmed only one clinical seizure between January 30, 2001 and March 26, 2001. The March 6, 2001 video-EEG correlated Camille’s brain activity with her movements, such that there is no doubt that she had one “clinical seizure.” Exhibit 9B. Judge Lettow’s opinion and order referenced testimony about this clinical seizure. Loving, 86 Fed. Cl. at 137 n.4.

In footnote 22, the undersigned intended to state that, more likely than not, Camille had seizures that were not observed. This statement, had it been made, would have conformed to the passage on page 9 of the slip opinion that notes “the number of clinical seizures depends, in part, on the degree of observation.” A finding that Camille was having seizures that were not “clinical seizures” is consistent with the record because during the 56 days in question, Camille was observed by medical personnel infrequently. See exhibit 7B at 206 (visit to a neurologist on Feb. 5, 2001); exhibit 12B at 242 (PET scan); exhibit 8B at 220 (admission form for hospitalization for the March 6, 2001 EEG). When medical personnel are not observing Camille, they cannot document a “clinical seizure.”

The undersigned CLARIFIES the July 30, 2009 ruling to make explicit that between January 30, 2001 and March 27, 2001, Camille experienced one seizure that was observed by medical personnel and recorded by EEG, that is, one “clinical seizure.” Any other seizures that Camille experienced were not “clinical seizures” because they were not observed by medical personnel and not confirmed by EEG.

To the extent that the Lovings’ motion requested the outcome of the July 30, 2009 ruling be changed due to an alleged conflict with Judge Lettow’s March 4, 2009 Opinion and Order, that requested relief is DENIED. The undersigned understood that Camille had “one clinical seizure,” notwithstanding the erroneous reference to “clinical seizures” in footnote 22. A conclusion of the July 30, 2009 ruling was that respondent had met her burden of establishing, by a preponderance of the evidence, that “Camille’s current condition is predominantly due to the

⁷ Upon review, this citation should be tr. 459:12-19, not tr. 458. Additionally, although the transcript at page 459 does state that 56 days had passed since her last clinical seizure, Camille actually had one clinical seizure on the March 6, 2001 video EEG. Exhibit 9B.

infantile spasms, which began in January 2001, and not due to the resumption of her infantile spasms following her third DTaP vaccination on March 27, 2001.” Ruling, slip op. at 24, 2009 WL 3094883, at *19. This conclusion was drawn from the entire record and did not rest exclusively upon a finding that before the March 27, 2001 vaccination, Camille had more than one “clinical seizure.”

III. Conclusion

Pursuant to the Lovings’ request, the undersigned has reconsidered how the July 30, 2009 ruling interpreted the respondent’s stipulation. For the reasons set forth above, the Lovings’ proposed interpretation of the stipulation is not what respondent intended. Thus, the Lovings are not entitled to any relief.

The undersigned has also reconsidered the findings of fact made in the July 30, 2009 ruling. These findings are not in conflict with Judge Lettow’s March 4, 2009 opinion and order. However, the undersigned has clarified the July 30, 2009 ruling as set forth above.

A status conference will be held on **March 25, 2010 at 11:00 Eastern Time**. The parties should be prepared to address the issues identified in the July 30, 2009 ruling.

IT IS SO ORDERED.

S/ Christian J. Moran
Christian J. Moran
Special Master