OFFICE OF SPECIAL MASTERS

BILL AND APRIL PARCELLS,
on behalf of their Deceased Daughter,
MACKENZIE PARCELLS

* Special Master Christian J. Moran
Petitioners,
* Filed: July 18, 2006

v.

* Onset decision; DTP vaccine;
SECRETARY OF THE DEPARTMENT * Death: Accuracy of written

SECRETARY OF THE DEPARTMENT * Death; Accuracy of written of HEALTH AND HUMAN SERVICES, * records vs. oral testimony

Mari C. Bush, Denver, Colorado for petitioners Lynn E. Ricciardella, Washington, D.C. for respondent

Respondent.

FINDINGS OF FACT - TO BE PUBLISHED¹

I. Introduction

Bill and April Parcells, the parents of MacKenzie Parcells, filed a petition pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq. Petitioners claim that a diptheria, tetanus and acellular pertussis ("DTaP") vaccination, given to MacKenzie on May 15,

¹ Vaccine Rule 18(b) states that 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, petitioner has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

2000, caused MacKenzie to suffer an encephalopathy.²

The Parcells are pursuing compensation under two theories: first, that MacKenzie suffered a "Table Injury" – that is, an injury falling within the Vaccine Injury Table – corresponding to one of her vaccinations, or second, that MacKenzie suffered an injury that was caused-in-fact by a vaccine. See Amended Petition ¶¶ 26, 27.

To prove a "Table Injury" claim, the Parcells must prove that MacKenzie suffered an encephalopathy within 72 hours of her DTaP vaccination. In support of their claim that MacKenzie displayed the symptoms of an encephalopathy within 72 hours of the vaccination, the Parcells submitted affidavits from MacKenzie's grandparents, family friends, and themselves.³ Exhibits 2-10. The Parcells rely solely upon these affidavits instead of medical records from that period because the medical records do not record the first seizure until May 25, 2000, ten days after vaccination. See Exhibit 14 at 13.

In its Report, Respondent denied that MacKenzie suffered any signs of an encephalopathy within 72 hours after vaccination. Respondent asserted that the contemporaneous medical records are not consistent with the testimony presented in the affidavits, in that the records do not reflect any change in behavior in the days following the vaccinations. Respondent's Report, filed pursuant to Vaccine Rule 4 and dated August 18, 2005, at 9-10.

² In their initial petition, filed May 14, 2003, the Parcells alleged that MacKenzie's encephalopathy caused a seizure disorder that delayed her development. Sadly, on February 20, 2004, MacKenzie died. Exhibit 56. Consequently, on May 7, 2004, the Parcells filed an amended petition alleging that the encephalopathy caused MacKenzie's death. The distinction between MacKenzie's injury and her death has no bearing on the issues discussed in this ruling.

³ Although Mr. Parcells submitted his own affidavit (exhibit 3) this affidavit is almost a verbatim copy of Mrs. Parcells' affidavit (exhibit 2). Because Mrs. Parcells observed more events, citations will be to her affidavit only.

To determine what symptoms, if any, MacKenzie displayed between her vaccination on May 15, 2000, and the seizure first recorded in the medical records on May 25, 2000, specifically focusing on the 72 hours following the vaccination, the undersigned special master held a hearing in Denver, Colorado on May 2, 2006. See Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 779-80 (2006); Skinner v. Sec'y of Health & Human Servs., 30 Fed. Cl. 402, 410 (1994). Whether contemporaneous medical records or later-given oral testimony is more persuasive is a determination that "is uniquely within the purview of the special master." Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

At this hearing, the special master heard testimony from four witnesses: Beverly Prigmore, MacKenzie's maternal grandmother; Karla Brunson, a family friend; April Parcells, MacKenzie's mother; and Bill Parcells, MacKenzie's father. Additionally, before the hearing, the special master reviewed all the exhibits filed by the Parcells.

The Vaccine Act permits a finding that the first symptom appeared within the time listed in the table, despite the lack of a notation in a contemporaneous medical record. In pertinent part, the Vaccine Act provides:

The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made

⁴ The purpose of the hearing was to find facts. The purpose was not to determine whether MacKenzie suffered an encephalopathy as defined at 42 C.F.R. § 100.3(b)(2)(i). See Order, dated November 17, 2005; Transcript of hearing ("Tr.") 143-46. Each party will have an opportunity to present the opinions of doctors as to whether the facts, as found in this ruling, meet the regulatory definition of encephalopathy.

only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did, in fact, occur within the time period described in the Vaccine Injury Table.

42 U.S.C. § 300aa-13(b)(2) (2006). The preponderance of the evidence standard requires that the Special Master "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 [special master] of the fact's existence." In re Winship, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring) (quoting F. James, Civil Procedure 250-51 (1965)).

In weighing divergent pieces of evidence, contemporaneous written medical records are usually more significant than oral testimony. <u>Cucuras v. Sec'y of Health & Human Servs.</u>, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, compelling oral testimony may be more persuasive than the written records. <u>Campbell</u>, 69 Fed. Cl. at 779 ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); <u>Camery v. Sec'y of Health & Human Servs.</u>, 42 Fed. Cl. 381, 391 (1998) (this rule "should not be applied inflexibly, because medical records may be incomplete or inaccurate"); <u>Murphy v. Sec'y of Health & Human Servs.</u>, 23 Cl. Ct. 726, 733 (1991), <u>aff'd</u>, 968 F.2d 1226 (Fed. Cir. 1992).

Generally, the reliability of medical records depends upon at least two different sets of individuals: the persons providing the information and the persons recording the information.⁵

⁵ One person performs both tasks occasionally. For example, a patient may fill out a questionnaire that includes a check box of symptoms. However, this document is usually the starting point for further investigation by the health care provider.

Theoretically, the records must be maintained and retrieved accurately as well. However, questions that could be answered by a document custodian are rarely raised.

First, medical records are only as accurate as the person providing the information. The ability to recount symptoms and problems to a doctor is comparable to a person's ability to testify in a court. Witnesses in court are competent to present their testimony when they possess four traits: (1) the ability to observe or to perceive events with their senses, (2) the ability to remember their observations or perceptions, (3) the ability to communicate these observations or perceptions, and (4) an appreciation for the obligation to tell the truth. See Michael H. Graham, 2 Handbook of Federal Evidence § 601.1 (6th ed. 2006).

In translating these abilities from the courtroom to a doctor's examination room, the fourth factor – honesty – will almost always be present. Because people are seeking assistance for an illness or injury, they are likely to be as forthcoming as possible. See Cucuras, 993 F.2d at 1528 ("With proper treatment hanging in the balance, accuracy has an extra premium."). However, due to anxiety, stress, or the nature of the illness or injury itself, the first three attributes (observation, memory, and communication) may be impaired when patients talk to doctors.

Second, the accuracy of medical records depends upon the person recording the information presented by the patient. Normally, health care providers document the patient's subjective history as well as the objective observations. This data is recorded to facilitate medical treatment and to substantiate requests for payment. Therefore, it is usually accurate. "Usually," of course, does not mean "always." Sometimes, a "symptom may have been relayed, but misreported or not recorded by the medical professional." Campbell, 69 Fed. Cl. at 779.

In this case, the Parcells contend that MacKenzie's medical records are deficient in both respects. First, they maintain that the histories that they provided when MacKenzie was

receiving medical treatment for seizures in late May 2000 and June 2000, are not accurate. The Parcells explain that either they did not perceive some of MacKenzie's behavior, particularly her body tensing during the staring spells, or, to the extent that they did observe some actions, especially her staring, they did not appreciate the significance of their observations and, therefore, did not communicate their perceptions to the doctors.

Second, the Parcells contend that they have consistently informed medical professionals that their daughter's problems began immediately after the vaccination. Yet, despite their statements, doctors who treated MacKenzie in May and June 2000, appear to have discounted their statements and not recorded them.

In contrast, Respondent maintains that the medical records accurately describe the medical problems that MacKenzie was facing at that time. Respondent's Report at 9-10; Tr. 10.

II. Background

The medical records summarize many facts about which the parties have no dispute.

MacKenzie was born on March 18, 2000. Pet. at ¶ 3. Within MacKenzie's first two months,

Ms. Parcells contacted MacKenzie's pediatrician, Dr. Rodney Yap, five times. Ms. Parcells was

concerned about matters that were relatively insignificant and did not last very long. On separate
dates, Ms. Parcells called Dr. Yap because MacKenzie was "gassy;" MacKenzie vomited after
breastfeeding; MacKenzie had yellow drainage from her right eye, which was puffy and swollen;
MacKenzie cried and screamed when she burped or passed gas; and MacKenzie was constipated.

Exhibit 14 at 5-6. Ms. Parcells believed that Dr. Yap was responsive to her concerns. Tr. 98.

None of these events had any long-lasting consequences.

During her first two months, MacKenzie developed appropriately. Exhibit 14 at 4;

exhibit 58 (affidavit of Dr. Rodney Yap, dated May 1, 2004) ¶¶ 6-7. According to her mother, MacKenzie attained some milestones on the early side of average. Tr. 47, 91; see also exhibit 5 (affidavit of Beverly Prigmore, dated March 31, 2003) ¶ 5. By the time MacKenzie reached two months old, she smiled, cooed, and recognized her parents' voices. Tr. 47. She also could control her head and was beginning to roll over from her stomach to her back. Tr. 47, 117; exhibit 2 (affidavit of April Parcells, dated May 2, 2003) ¶ 11; exhibit 5 ¶ 6; exhibit 8 (affidavit of Pat Parcells, dated April 14, 2003) ¶¶ 6-7.

On May 15, 2000, MacKenzie received a dose of the DTaP vaccines. She also received a dose of the haemoplilis influenza (Hib), inactivated polio and hepatitis B vaccines.⁶ Exhibit 14 at 4; 10. How MacKenzie responded to the vaccinations is disputed and will be discussed in more detail below.

The Parcells remained at their home in Wichita Falls, Texas for the three days following the vaccination. On May 18, 2000, Mrs. Parcells and MacKenzie flew to Denver, Colorado to look for houses because Mr. Parcells' employer (United Airlines) was transferring him there. While in Denver, Ms. Parcells and MacKenzie stayed first at the home of Ms. Karla Brunson for a few days. Tr. 32. Then, beginning on May 20, 2000, Ms. Parcells and MacKenzie stayed with Ms. Parcells' parents, Mr. and Mrs. Prigmore. Tr. 24. While in Colorado, Ms. Parcells called Dr. Yap's office because MacKenzie's eye infection was worsening. Exhibit 14 at 6. The notes from this telephone call do not show that Ms. Parcells was concerned about staring spells,

⁶ For purposes of determining whether MacKenzie suffered a "table injury," these three vaccines are not relevant. For the inactived polio vaccine and for hepatitis B vaccine, only one condition (anaphylaxis or anaphylactic shock) is listed on the table and there is no evidence that MacKenzie suffered from it. For Hib, there is no condition specified for compensation.

decreased head control, or increased fussiness. Tr. 84-85. Ms. Parcells and MacKenzie stayed with the Prigmores in Colorado for a few more days and then returned to Wichita Falls, Texas on May 25, 2006.

After arriving in Wichita Falls on May 25, 2000, ten days after vaccination, Ms. Parcells was leaving a friend's home in the afternoon and went to carry MacKenzie to her car seat. When Ms. Parcells reached to pick up MacKenzie, MacKenzie's eyes were fixed in one direction.

When Ms. Parcells touched her daughter, MacKenzie's neck muscles were rigid. For a few moments, MacKenzie did not respond to her mother. Then, the "staring spell" episode ended.

Exhibit 2 ¶ 20; Exhibit 15 at 6 (emergency room report, dated May 26, 2005); 7 Tr. 60-61, 72-73.

Later that day, Ms. Parcells brought MacKenzie to the emergency room, where she was admitted at approximately 7:30 p.m. Exhibit 15 at 1, 4. The chief complaint was decreased level of consciousness. <u>Id.</u> at 1. The notes from a triage nurse reports that Ms. Parcells stated that MacKenzie's stiffness and eye fluttering lasted 20 seconds. <u>Id.</u> at 4. A doctor examined MacKenzie and reviewed some laboratory data. The doctor opined that MacKenzie probably suffered some reflux.⁸ He instructed Ms. Parcells to follow up with Dr. Yap in the morning. <u>Id.</u> at 7. MacKenzie was discharged from the emergency room at approximately 11:00 p.m. <u>Id.</u> at 5.

The next morning, on May 26, 2000 at approximately 8:00 a.m., Ms. Parcells called

⁷ This report is dated May 26, 2000, which is the date it was dictated. However, the report is memorializing events that took place on May 25, 2000.

⁸ Ms. Parcells testified that she attempted to tell medical personnel about previous episodes. However, according to Ms. Parcells, they were not interested in this information. Tr. 87.

Dr. Yap's office to schedule an appointment for MacKenzie. Exhibit 2 ¶ 22.9 When the call ended, Ms. Parcells noticed that MacKenzie was having another staring spell. She called Dr. Yap's office again and she was told to bring in MacKenzie immediately. Tr. 87.

Dr. Yap saw MacKenzie on the morning of May 26, 2000. Exhibit 14 at 7, Exhibit 53. His goal was to determine whether MacKenzie was having seizures. His plan included the scheduling of an electroencephalogram ("EEG") at 12:30 p.m. that day. Id.; see also Tr. 107-08.

While in the waiting room for the EEG, MacKenzie suffered a seizure, lasting two minutes. Exhibit 14 at 19; Exhibit 15 at 8; Tr. 107-08. Dr. Yap admitted her to the hospital. In the hospital, Dr. Yap prescribed phenobarbital to control MacKenzie's seizures. Exhibit 15 at 3. She did not experience any seizures for the next few days and she was discharged from the hospital on May 28, 2000. Exhibit 15 at 3. Dr. Yap noted that they next were scheduled to see Dr. McGlothlan. Exhibit 14 at 7.

On May 31, 2000, the Parcells and Mrs. Prigmore took MacKenzie to see

Dr. McGlothlan, a pediatric neurologist associated with Cook Children's Medical Center in

Ft. Worth, Texas. Tr. 25-26, 89. Dr. McGlothlan described the adults as "excellent historians."

Exhibit 14 at 19. According to Dr. McGlothlan's report, MacKenzie "was in her usual state of good health until one day last week." Id. In the section about developmental history,

Dr. McGlothlan states that she "is fixing and following visually and smiling socially. She can pick up her head from a prone position." Id. at 20. Dr. McGlothlan discussed two possible reasons for MacKenzie's episodes. He thought that they could be epileptic seizures or part of

 $^{^9}$ There are two paragraphs numbered "22" in this affidavit. This citation is to the second \P 22.

transitional sleep. Id. at 21.

On June 2, 2000, Ms. Parcells with MacKenzie's paternal grandmother began driving with MacKenzie from Wichita Falls to Ft. Worth. Ms. Parcells wanted to stay in Ft. Worth in case MacKenzie had more problems. Exhibit 16 at 5; exhibit 2 ¶ 24; exhibit 8 ¶ 8. On this day, MacKenzie had at least seven seizures that lasted one minute each. Exhibit 49 at 1, 4. On the way to Ft. Worth, MacKenzie had a seizure in the car and Ms. Parcells brought her to an emergency room in Bowie. Exhibit 16 at 5; exhibit 49. After MacKenzie was stabilized, the Parcells left the emergency room and continued to Ft. Worth with instructions to call a doctor the next day.

While traveling from the emergency room in Bowie to Ft. Worth, MacKenzie had yet another seizure. Ms. Parcells brought her to the emergency room in Denton. Exhibit 16 at 5; exhibit 46. From Denton, an ambulance transported MacKenzie to Cook's Children Medical Center in Ft. Worth, where she was admitted shortly after midnight on June 3, 2000.

While in Cook's Children Medical Center, MacKenzie was seen by Dr. Howard Kelfer. Exhibit 16 at 5. Dr. Kelfer noted that Ms. Parcells was "an excellent historian." Dr. Kelfer stated that the seizures began nine days before June 3, 2000, which is May 25, 2000. As part of his neurological examination, Dr. Kelfer stated that MacKenzie "is visually alert and follows horizontally and vertically. Head and trunk control appear appropriately developed for age." Dr. Kelfer's impression was that the seizures were occurring "in the context of a neurologically intact baby." Dr. Kelfer ordered an EEG. Exhibit 16 at 6. The EEG detected two seizures that

¹⁰ Ms. Parcells testified that she told doctors at Cook Children's Medical Center that what she knew was a seizure started on May 25, 2000, "but that the episodes had begun immediately after immunizations." Tr. 92.

were localized in the right occipital region. Exhibit 16 at 3, 10.

On June 4, 2000, Dr. Kelfer discharged MacKenzie. He stated that at her discharge examination, MacKenzie was "alert" and had "no focal deficit." He noted that the Parcells were planning to see Dr. Wayne Langburt, a doctor in Colorado, on June 12, 2000. Exhibit 16 at 23.

Dr. Langburt, a pediatric neurologist who works at Colorado Neurological Services, P.C., examined MacKenzie. Tr. 94. His report states "MacKenzie seems to be developmentally intact, by history. She rolls from front to back. . . . Parents feel that she does look around and respond to visual and auditory stimuli." Exhibit 35 at 147. Dr. Langburt's report describes the history of MacKenzie's seizures as starting on May 25, 2000. When he saw her, MacKenzie was having 12-20 clusters of seizures that lasted from 20 seconds to two minutes. Dr. Langburt observed events consistent with subtle seizures during his examination. <u>Id.</u> at 147-48. Dr. Langburt stated that the etiology of MacKenzie's frequent, intractable seizures was "not known." <u>Id.</u> at 148.

On June 13, 2000, Ms. Parcells brought MacKenzie to the emergency room at Memorial Hospital in Colorado Springs, Colorado. Exhibit 18 at 1-4. The notes from the emergency room state that Ms. Parcells stated that MacKenzie had 20 seizures that day. Medical personnel observed five seizures in less than one hour. <u>Id.</u> at 2. She was transferred from Memorial Hospital to Children's Hospital in Denver.

MacKenzie was admitted to Children's Hospital on June 13, 2000, shortly before midnight. Exhibit 18 at 2. Ms. Parcells completed an intake form. On this form, Ms. Parcells described the history of MacKenzie's illness as the "first seizure" on May 25, 2000. Ms. Parcells indicates that MacKenzie is able to "turn over." MacKenzie also could "see well," "hear well," and "babble." Exhibit 18 at 4-5; Tr. 95-97.

After being in the hospital for slightly more than one month, MacKenzie was discharged. Exhibit 18 at 7. While in the hospital, on June 28, 2000, MacKenzie had an MRI that showed diffuse brain atrophy. Exhibit 35 at 149. An interim report, dated July 15, 2000, states that MacKenzie "was smiling, cooing, reaching, tracking at appropriate ages, and now has noted developmental regression secondary to these seizures of the age-appropriate developmental activities currently noticed." Exhibit 16 at 27. The discharge report notes that MacKenzie's seizures began "around 05/25/2000, about 7-10 days after her well child check with immunizations given." Exhibit 18 at 7.¹¹

After MacKenzie left Children's Hospital in Denver, she continued to see doctors throughout the country. Various treatments did not help MacKenzie for long. Eventually and sadly, MacKenzie died on February 20, 2004, about one month before her fourth birthday.

III. Discussion

To receive compensation for MacKenzie's death, the Parcells must establish that her death was a consequence of the vaccination. Section 13(a)(1)(A), 11(c)(1)(C)(ii). The Parcells may meet this standard in either of two ways. First, they can establish that MacKenzie experienced, within the appropriate time, an injury listed in the Vaccine Injury Table, ¹² and, prove that MacKenzie's death was a sequela of the injury. Alternatively, the Parcells can establish that the vaccines were the cause in fact of her injury and that this injury led to MacKenzie's death. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed.

The reference to "immunization" is consistent with the testimony that the Parcells told doctors in Colorado that MacKenzie's problems began immediately following vaccination. Tr. 22, 75.

¹² 42 C.F.R. § 100.3

Cir. 2006). Here, as stated previously, the Parcells are attempting to establish that MacKenzie suffered an encephalopathy within 72 hours of her receipt of the DTaP vaccination. Thus, the events of the first three days after vaccination are determinative of their ability to prove that claim.

Through testimony, either presented through affidavits or elicited in the hearing, the Parcells claim that MacKenzie suffered various problems in the first 72 hours after vaccination. These include: 1) prolonged and intense crying, 2) a knot on her thigh, 3) difficulty eating and sleeping, 4) a loss of interaction and less smiling / cooing / laughing, 5) staring spells, 6) tongue thrusting, and 7) a diminished (or loss of the) ability to control her head and to track objects. As pointed out above, no medical record created within the first 72 hours documents these problems. An analysis of each claim follows.

1. <u>Prolonged and intense crying</u>

The Parcells have established that MacKenzie cried extensively beginning the night of May 15, 2000. The earliest affidavits state that MacKenzie had a shrill cry that night. Exhibit 2 ¶ 17; exhibit 13 ¶ 13. Ms. Parcells described in extensive detail her unsuccessful efforts to calm MacKenzie. Tr. 52-58. Mr. Parcells arrived home from work in the middle of the night and found his wife crying because their daughter was inconsolable. Tr. 119-22. Finding one's wife and two month old daughter in tears is such a significant event that Mr. Parcells' testimony is credited as accurate. In addition, the Parcells have established that MacKenzie cried more frequently and with a higher, more shrill cry after the vaccination.

2. A knot on her thigh

The Parcells also have established that MacKenzie had a red knot on her thigh in the spot

where the vaccination was injected into her. Ms. Parcells' first affidavit again describes MacKenzie as having a knot. Exhibit 2 ¶ 17. As discussed in more detail below, Ms. Parcells expressed concerns about MacKenzie to both Mrs. Prigmore and Ms. Brunson. Both of her confidants submitted affidavits in which they stated Ms. Parcells mentioned that MacKenzie had a red knot on her thigh. Exhibit 4 ¶¶ 10-11, 13; exhibit 5 ¶ 12. Mrs. Prigmore and Ms. Brunson repeated this information during their testimony. Tr. 13, 30. Finally, red knots are among the most common, albeit minor, consequences of vaccinations.

3. <u>Difficulty eating and sleeping</u>

The Parcells have also established that MacKenzie did not sleep as well and did not eat as well after her May 15, 2000 vaccination. Ms. Parcells did not include these features in her original affidavit. However, Ms. Parcells' third affidavit lists them. Exhibit 66 ¶ 20, 22. She also testified about these problems. Tr. 54, 58, 63, 99-100, 106-07. In addition, both Mrs. Prigmore and Ms. Brunson testified that Ms. Parcells told them, at the time, that MacKenzie was not sleeping or eating. Tr. 18, 25, 32. Not sleeping, not eating, and much crying are commonly associated with one another in two month olds. Crying can prevent the child from sleeping and lack of sleep may make the child not want to eat.

Corroboration that MacKenzie suffered from extra crying, poor sleeping, poor eating and a red knot on her thigh can be found in the contemporaneous medical records, although the corroboration is less direct than usual. In the first two days immediately after vaccination,

¹³ Ms. Parcells also did not list difficulty sleeping and eating in her second affidavit, dated May 1, 2004 (exhibit 55). However, that affidavit appears to be an attempt to establish the foundation for a videotape, which was submitted as exhibit 59. Because the second affidavit did not attempt to describe MacKenzie's problems comprehensively, the omission of certain items is understandable.

MacKenzie was suffering from these problems. Ms. Parcells called her mother and her friend to ask for advice. Although both Mrs. Prigmore and Ms. Brunson tried to allay Ms. Parcells' concerns initially, both began to have increased concerns about MacKenzie when she did not improve quickly. Eventually Mrs. Prigmore and Ms. Brunson suggested that Ms. Parcells call MacKenzie's pediatrician. Tr. 25, 38.

Ms. Parcells discussed whether to call Dr. Yap with her husband the night of May 17, 2000. Tr. 129. Ms. Parcells wanted to call the doctor because on May 18, 2000, she was taking MacKenzie with her on an airplane trip to Denver, Colorado. Tr. 65. The circumstances (being advised to call the doctor by your mother and friend and facing travel with an abnormally fussy two month old child) strongly suggest that Ms. Parcells is likely to have called Dr. Yap's office. Ms. Parcells testified that she called Dr. Yap's office on May 18, 2000, and told the woman answering the telephone that MacKenzie was "running a low-grade fever, real fussy, still warm [and] got a knot at the thigh." Tr. 66; see also Tr. 83, 99-100 (MacKenzie was "not sleeping well and not eating well."). According to Ms. Parcells, the woman from Dr. Yap's office told her that these problems were standard reactions to immunizations and not to worry. Id.

It is more likely than not that the records produced by Dr. Yap confirm Ms. Parcells' testimony. Many pages are titled "PROGRESS RECORD" and contain lines on which Dr. Yap could write his observations. One page contains three slips of paper documenting phone messages that were attached to MacKenzie's file. The third phone message, which is dated May 22, 2000, is placed over an entry that in the margin reads "5/18." Given that the person answering Ms. Parcells' call dismissed Ms. Parcells' concerns, it is likely that the person began taking notes of the conversation by first indicating the date in the margin. However, when the

person learned that Ms. Parcells' concerns were not significant (as viewed by the person answering the phone), the person stopped recording the information. Nevertheless, the margin notation "5/18" confirms that Ms. Parcells did relay (or attempt to relay) her concerns about MacKenzie to Dr. Yap.¹⁴

4. <u>A loss of interaction, and less smiling / cooing / laughing than prior to the vaccine</u>
In addition to the other traits discussed above, the Parcells contend that MacKenzie changed in how she interacted with other people. Specifically, they contend that MacKenzie

The evidence demonstrates that MacKenzie smiled less and cooed less in the 72 hours following vaccination. As discussed above, the Parcells have established that MacKenzie was more fussy, cried more frequently, and had difficulty eating and sleeping in the first three days. In short, MacKenzie was an unhappy baby. Logically, an unhappy, fussy baby will not smile and coo as much. The testimony at the hearing also described MacKenzie's diminished smiling and cooing. Tr. 56, 139; see also exhibit 66 ¶ 18.

ability to smile and to coo was impaired after the vaccination.¹⁵

The evidence consistently demonstrates that MacKenzie did not lose her ability to smile

¹⁴ This incident also proves that a "symptom may have been relayed, but misreported or not recorded by the medical professional." <u>Campbell</u>, 69 Fed. Cl. at 779.

The Parcells attempt to frame the question about MacKenzie's abilities to laugh, to coo and to smile in black and white terms. They assert that after the vaccination, MacKenzie stopped these activities entirely. Exhibit $66 \, \P \, 18$ ("MacKenzie immediately stopped making the cooing sound."); tr. 82, 139.

This assertion is not credible because other evidence shows that MacKenzie did coo, smile and laugh. The Parcells themselves recognize that in the two or three weeks after vaccination, MacKenzie still smiled (just less than usual) and still cooed (just less than usual). Tr. 90.

and/or to coo. Ms. Brunson stated that she observed MacKenzie smiling, laughing, and cooing during the visit to her home starting on May 18, 2000. Exhibit 4 ¶ 15; tr. 34-35. However, Ms. Brunson also said that these instances were "very few." Also, Dr. McGlothlan stated that MacKenzie was "smiling socially." Exhibit 16 at 20. Dr. McGlothlan's observation that MacKenzie displayed this ability does not contradict her parents' assertion that she was smiling less.

In regards to the other claims, the Parcells have not met their burden of proving the various symptoms started within 72 hours.

5. Staring spells

The Parcells failed to establish that MacKenzie suffered from staring spells within the first 72 hours. Considered as a whole, the evidence establishes that it is more likely than not that MacKenzie did not experience staring spells within the first 72 hours. ¹⁶ First, the contemporaneous medical records do not indicate that the Parcells notified Dr. Yap about this problem. Even when Ms. Parcells described the telephone call on May 18, 2006, which was not documented by the person answering the telephone, Ms. Parcells did not testify that she informed this person that MacKenzie was suffering from staring spells. Tr. 66, 83, 99-100. It is unlikely that Ms. Parcells mentioned staring spells in this conversation because staring spells — unlike the afflictions that more commonly afflict two month olds, such as, poor sleeping, poor eating,

¹⁶ According to the Federal Circuit, "close calls regarding causation are resolved in favor of injured claimants." <u>Althen v. Sec'y of Health & Human Servs.</u>, 418 F.3d 1274, 1280 (Fed. Cir. 2005). The phrase "close call" suggests that the evidence is in equipoise. <u>See Ortiz v. Principi</u>, 274 F.3d 1361, 1365 (Fed. Cir. 2001) (interpreting 38 U.S.C. § 5107). Here, although the Parcells made a solid case, the evidence preponderates against their claim for the reasons stated in the text.

and general fussiness — are likely to be documented and to prompt further investigation.

The Parcells attempt to counter the lack of documentation with two arguments. First, there is a question of an untrained person's ability to observe a seizure. Second, there is a question of their ability to communicate their observations to a doctor because they did not appreciate what they observed.

There is some merit to the assertion that identifying a "seizure" would have been hard for the Parcells. As Dr. Yap declared in his affidavit, "subtle seizure behavior can be very difficult for parents to detect, especially for first time parents or parents who do not have any experience with seizures in infants." Exhibit $58 \, \P \, 9$. The lay witnesses made the same point about MacKenzie's seizures. Exhibit $5 \, \P \, 5$.

However, identifying "seizures" as "seizures" is not important. It is more important for care-givers to observe behavior, such as staring spells. Medical professionals, such as Dr. Yap, can diagnose the seizure from the information presented to them.

The contemporaneous medical records contain no information that the Parcells told MacKenzie's doctors that they observed her having staring spells immediately after the vaccinations. The record shows that Ms. Parcells was a dedicated parent. For example, she noticed when MacKenzie did not have a bowel movement for a week. Exhibit 14 at 6; see also Tr. 55 (Ms. Parcells' describing herself as "anal" in monitoring MacKenzie's progress). Because Ms. Parcells was so dedicated and loving, she would have communicated any significant deviations in expected behavior to a doctor.

The report presented by Dr. McGlothlan is persuasive evidence that MacKenzie did not experience any staring spells before the seizure on May 25, 2000. Both parents and Mrs.

Prigmore brought MacKenzie to Dr. McGlothlan, who commented that they "are excellent historians and very concerned."

The context for Dr. McGlothlan's examination indicates that if the Parcells had observed any staring spells, they would have told Dr. McGlothlan about them. Dr. McGlothlan examined MacKenzie on May 31, 2000, only 16 days after her vaccination. Thus, the details would be fresh in the Parcells' memory.

Moreover, by May 31, 2000, the Parcells had observed enough of MacKenzie's staring spells to note that the episodes occurred falling into or waking from sleep. Thus, the Parcells knew that behavior, which they may have dismissed or ignored as normal for a two month old a few weeks earlier, could have clinical significance.

Finally, the Parcells had an opportunity to tell Dr. McGlothlan about the staring spells. Dr. McGlothlan's report states that he had a "long discussion" with them. Exhibit 14 at 21. Mr. Parcells estimated that their meeting with Dr. McGlothlan lasted 60-90 minutes. Tr. 141. In contrast to a visit to an emergency room in which the focus could be on the patient's immediate problems, the visit to Dr. McGlothlan was free of that pressure. The Parcells could prepare for the scheduled appointment and present all the changes in her behavior. For all these reasons, Dr. McGlothlan's report is persuasive evidence about MacKenzie's condition after May 15, 2000.

Dr. McGlothlan records the Parcells as telling him that "MacKenzie was in her usually good state of health until one day last week." For the reasons explained above, Dr. McGlothlan's report is powerful evidence standing by itself. It takes on additional weight because it is consistent with other contemporaneous medical records.

The other records that were created within two months of MacKenzie's vaccination indicate that the seizures started on May 25, 2000. For example, Dr. Kelfer, who saw MacKenzie at Cook County Medical Center in Ft. Worth, states that the seizures started then. Exhibit 16 at 6. Dr. Langburt, a pediatric neurologist, who saw MacKenzie in Colorado Springs states that the seizures began on May 25, 2000. Exhibit 35 at 147. The admission record to Children's Hospital in Denver, which was filled out by Ms. Parcells, shows that Ms. Parcells said that the seizures began on May 25, 2000. Exhibit 18 at 4-5.

Although the Parcells argue that they told doctors that MacKenzie's problems began right after immunization, this testimony is not reliable. While one doctor may have failed to document every complaint the Parcells listed, the Parcells brought MacKenzie to at least four different doctors in the four weeks after vaccination. At least two doctors (Dr. McGlothlan and Dr. Langburt) are pediatric neurologists, who have greater expertise and greater sensitivity to seizures. However, none of the doctors noted that staring spells preceded the first seizure by several days. It is highly unlikely that all four doctors would have failed to record the Parcells' observations.

In addition to the conflict with contemporaneous medical records, the Parcells' testimony about the onset of staring spells cannot be credited because the details about MacKenzie's staring spells were not consistent. Murphy, 23 Cl. Ct. at 733, Blutstein v. Sec'y of Health & Human Servs., No. 90-2808V, 1998 WL 408611 *5 (Fed. Cl. Spec. Mstr. June 30, 1998) (stating that to overcome the presumption that written records are accurate, testimony is required to be "consistent, clear, cogent, and compelling."). In Ms. Parcells' first affidavit, she did not provide any information about either the frequency or the duration of the starting spells. Exhibit 2 ¶ 18.

In her third affidavit, Ms. Parcells stated that MacKenzie had "at least six" seizures on May 15, 2000. On each of the next two days, MacKenzie had "at least fifteen seizures." Ms. Parcells estimated that the duration of the seizures varied from 30 seconds to two minutes. Ms. Parcells concluded that within the first 72 hours MacKenzie "experienced at least 30 minutes of seizure activity." Exhibit 66 ¶ 25.

At the hearing, Ms. Parcells stated that the frequency of the staring spells increased and by the third day, she "was seeing upwards close to 10 to 15 a day." Tr. 104. As for duration, the staring spells started lasting about 10 seconds but then gradually increased to 30 seconds, or perhaps 45 seconds. Tr. 62, 80, 103-04.¹⁷ Mr. Parcells testified that the staring spells lasted "a few to several seconds." Tr. 124. He stated that MacKenzie may have had as many as "a half-dozen" episodes. Tr. 125.

The Parcells are sincere in the sense that they genuinely believe these events happened. Despite this sincerity, their testimony is not reliable. If the Parcells can remember so many details about six years after the events, the Parcells would have known this same information when they met with Dr. McGlothlan, Dr. Kelfer, and Dr. Langburt within two months after the vaccination. Being concerned parents as they were, the Parcells would have told the doctors about every change in MacKenzie's behavior.

Finally, the testimony of Mrs. Prigmore and Ms. Brunson is not consistent with an assertion that MacKenzie began experiencing staring spells within the three days immediately

¹⁷ Ms. Parcells did testify that MacKenzie's staring spells lasted two minutes. Tr. 62. In light of the other testimony saying that staring spells within the first three days lasted, at most, 45 seconds, Ms. Parcells appears to have provided information about how long the staring spells lasted more than three days after vaccination.

after vaccination. Ms. Brunson had an opportunity to observe MacKenzie on days four and five, while Ms. Parcells and MacKenzie were staying with them. Ms. Brunson had not seen MacKenzie in person until May 18 and then did not see MacKenzie again until mid June, after MacKenzie had been hospitalized twice. Exhibit 4 ¶¶ 5, 12, 17; tr. 41. Thus, Ms. Brunson's recollections about her initial observations of MacKenzie are unlikely to be confused with perceptions made at other times. Although Ms. Brunson thought that MacKenzie was fussy, she did not observe any staring spells. Tr. 44.

Mrs. Prigmore also did not remember observing any staring spells. Tr. 21. Ms. Parcells and MacKenzie stayed at Mrs. Prigmore's house from May 20th until May 25th when they returned to Texas. Given this opportunity to watch MacKenzie and to interact with her, Mrs. Prigmore's lack of observation strongly suggests that MacKenzie did not have any staring spells at her house. But see exhibit 6 (Affidavit of Thomas E. Prigmore, dated March 31, 2003) ¶ 11.

In sum, the Parcells have not met their burden of establishing that MacKenzie experienced any staring spells within the first 72 hours.

6. Tongue thrusting

The Parcells have not established that MacKenzie thrust her tongue in a rhythmic pattern in the first 72 hours after vaccination. There is no question that at some point MacKenzie began thrusting her tongue out of her mouth. The videotape, exhibit 59, clearly shows MacKenzie thrusting her tongue on an unspecified date. Thus, the question is when did the tongue thrusting begin.

Ms. Parcells and Mr. Parcells testified that MacKenzie started thrusting her tongue in the first 72 hours after vaccination. Tr. 67, 72, 129-30. Mrs. Prigmore supports this claim by

testifying that she saw MacKenzie thrust her tongue during their visit to Colorado from May 20-25. Tr. 18-19.

However, this testimony is not reliable when compared to other evidence. First, the contemporaneous medical records do not indicate MacKenzie was thrusting her tongue. The primary evidence, again, is the examination by Dr. McGlothlan. As explained above, Dr. McGlothlan's examination was conducted when the Parcells had an opportunity to present all of MacKenzie's problems to a specialist. If MacKenzie were thrusting her tongue, the Parcells would have mentioned it. In addition, Dr. McGlothlan's report indicates that he examined MacKenzie's head, eyes, ears, nose and throat. Exhibit 69 at 6. The lack of any comment about MacKenzie's mouth or tongue suggests that he found this part of MacKenzie to be normal.

Second, earlier affidavits from the Parcells and Mrs. Prigmore fail to mention tongue thrusting. <u>See</u> exhibits 2, 3, 5, 55, 66, and 67.

Third, Ms. Brunson, who saw MacKenzie between three and five days after vaccination, did not testify that she observed any tongue thrusting. Tr. 27-44. Ms. Brunson enjoyed a fair opportunity to notice any tongue thrusting because each spent most of a few days with MacKenzie. Tr. 43. However, she did not see any problem. Her failure to testify about tongue thrusting between May 18 and May 20, 2000, strongly suggests that MacKenzie was not thrusting her tongue between May 15 and May 18, 2000.

Fourth, the videotape, itself, suggests that the tongue thrusting began after the staring spells / seizures began. The Parcells began to videotape MacKenzie's staring spells after Dr. Yap suggested other doctors would want to see the staring spells. Tr. 70. The videotape shows several staring spells. Only the last episode, which follows a portion dated June 2, 2000, shows

tongue thrusting. Exhibit 59. This chronology strongly suggests that MacKenzie's tongue thrusting began only after MacKenzie's staring spells had continued for at least a week.

The balance of the evidence leads to the conclusion that MacKenzie did not start thrusting her tongue within the first 72 hours of vaccination.

7. A diminished (or loss of the) ability to track objects and to control her head.

In addition to staring spells, the Parcells contend that MacKenzie changed in how she interacted with the world. Specifically, the Parcells assert that she had a decreased ability to track objects. The Parcells also say that she had a decreased ability to hold up her head.¹⁸

The Parcells have not met their burden of establishing that MacKenzie's abilities to track objects and her ability to support her head diminished within the first 72 hours. The medical records close in time to the vaccination contradict the Parcells' assertions.

The records from MacKenzie's hospitalization on May 26, 2000, do not indicate that MacKenzie could not track objects. They also do not indicate that MacKenzie could not support her head. Exhibit 15. Dr. Yap both admitted MacKenzie to the hospital and then was the attending physician for her while in the hospital. Exhibit 15 at 2. Dr. Yap also prepared the discharge summary. Exhibit 15 at 3. If her ability to track objects had decreased, Dr. Yap would have documented his observation because he was familiar with her.

Dr. McGlothlan's report is even stronger evidence that MacKenzie's abilities were not diminished. Dr. McGlothlan wrote that MacKenzie "did fix and follow on my face and had full

¹⁸ Ms. Parcells also suggests that MacKenzie immediately lost these abilities entirely. Exhibit 66 ¶¶ 17, 21; tr. 55. This testimony is exaggerated. As discussed in the text, MacKenzie retained at least some ability to track objects for several weeks. Moreover, even the Parcells recognize that MacKenzie's ability to track objects merely decreased. Tr. 90, 127 (stating that MacKenzie's looks at a toy were "fleeting").

extraocular movements that were conjugate." He also stated that "[t]here is no evidence of head lag." Exhibit 14 at 21. Dr. McGlothlan drew these conclusions based upon his personal examination of her. Tr. 90. The findings on an objective examination by a qualified specialist cannot easily be discounted. If MacKenzie were having problems tracking objects and/or lifting her head, Dr. McGlothlan would have made some notation, and certainly would not have made observations to the contrary.

The accuracy of Dr. McGlothlan's description is reinforced by the findings of Dr. Kelfer, who examined MacKenzie at the Cook Children's Medical Center, approximately three days after Dr. McGlothlan. Dr. Kelfer stated that MacKenzie "is visually alert and follows horizontally and vertically. Head and trunk control appear appropriately developed for age." Exhibit 16 at 6.

Because Dr. McGlothlan and Dr. Kelfer indicate that MacKenzie was normal, in regards to her ability to track objects and her ability to support her head, on May 31, 2000, and on June 3, 2000, respectively, it is likely that MacKenzie was also normal on May 16, 2000, the day after vaccination. Therefore, the Parcells have not met their burden of proving that the onset of MacKenzie's problems with tracking objects or holding up her head started within the first three days of vaccination.

Although the special master has rejected some of the Parcells' claims about how MacKenzie changed within the first 72 hours, the special master believes that the Parcells tried to testify accurately and honestly. However, the passage of time has not helped their memories. They remember that certain events occurred, but seems to have difficulty establishing when they occurred. See Howard v. Sec'y of Health & Human Servs., No. 03-550V, 2006 WL 932281

(Fed. Cl. Spec. Mstr. Mar. 22, 2006).

IV. SUMMARY

The undersigned special master expressly finds the following facts:

- 1. MacKenzie Parcells was born on March 18, 2000.
- 2. During her first two months, MacKenzie developed normally.
- 3. On May 15, 2000, MacKenzie received a dose of the diphtheria, tetanus and acellular pertussis vaccines. She also received a dose of the haemoplilis influenza, inactivated polio and hepatitis B vaccines.
- 4. Within the first 72 hours after vaccination, MacKenzie cried at a higher, more shrill level. Within the first 72 hours after vaccination, MacKenzie had a red knot on her thigh at the site of the vaccination.
- 5. Within 72 hours of the vaccination, MacKenzie had difficulty sleeping, difficulty eating, and was generally fussy. Within the first 72 hours after vaccination,

 MacKenzie smiled less frequently and cooed less often when compared to the amount of smiling and cooing before the vaccination.
- 6. Within the first 72 hours of vaccination, MacKenzie did not experience any "staring spells."
- 7. Within the first 72 hours of vaccination, MacKenzie did not thrust her tongue outside of her mouth.
- 8. Within the first 72 hours of vaccination, MacKenzie's ability to track objects and her ability to lift her head was not impaired.

The parties are instructed to call my law clerk,	Shana Siesser, at (202) 357-6358, to
schedule the next status conference.	
IT IS SO ORDERED.	
	Christian J. Moran Special Master