OFFICE OF THE SPECIAL MASTERS
March 28, 1997

JAMES C. GROSS, by his Mother and Next Friend, JOELLEN BASS,	*	
Petitioner,	*	
vs.	*	No. 95-204V
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Ronald C. Homer, Boston, MA, for petitioner.

Eleanor A. Barry, Washington, DC, for respondent.

DECISION AND ORDER

MILLMAN, Special Master

Joellen Bass filed a petition on behalf of her son James C. Gross (hereinafter, "James") on March 9, 1995 for compensation under the National Childhood Vaccine Injury Act of 1986[(1)] (hereinafter, the "Vaccine Act" or the "Act"). Petitioner has satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that she has not previously collected an award or settlement of a civil action for damages arising from the vaccine injury, that the DT vaccination was administered to James in the United States, and that she has incurred $1,000.00 in unreimbursable medical expenses prior to filing her petition.

Petitioner initially alleged anaphylaxis, anaphylactic shock, encephalopathy, shock collapse, hypotonic-hyporesponsive collapse, residual seizure disorder, neurological sequelae and "other symptoms and diseases." At trial, petitioner alleged encephalopathy and, in the alternative, significant aggravation. 42 U.S.C. §§ 300aa-11(c)(1)(C)(I) and 14(a)(I)(B) and (E). Respondent denies that James had

encephalopathy or significant aggravation following a diphtheria-tetanus vaccination.

The court held a hearing in this case on February 7, 1997. Testifying for petitioner were Joellen Bass, Melissa J. Hergt, and Dr. John Tilelli. Testifying for respondent was Dr. Jay E. Selman.

FACTS

James was born on August 11, 1976. He received a diphtheria-tetanus vaccination on February 7, 1994 when he was seventeen and a half years old. Med. recs. at Ex. 6, p.4.

His earlier medical records depict a child with abnormalities. On November 12, 1979, when James was three years and three months of age, Dr. Ned Wilson, his pediatrician, recorded that James did not talk and said only a few words. Med. recs. at Ex. 5, p. 4.

On March 12, 1980, James visited Grant-Blackford Mental Health, Inc. at the age of three years and eight months. The records note pronounced delay in speech onset, excessive rate of psychomotor activity, short attention span, a high level of distractibility, a marked tendency to change tasks frequently, emotional distance, random nodding of his head, grunting, and pointing in response to all questions. Med. recs. at Ex. 12, p. 1.

On March 15, 1982, Grant-Blackford Developmental Center program director David M. Congdon wrote to Dr. Ned Wilson that James had severe delays. Med. recs. at Ex. 5, p. 6.

On February 7, 1994, Dr. C.E. Thornton of Mashpee Medical Associates recorded that James had a neurologic deficit and would be referred to Dr. Leahy. He gave James a diphtheria-tetanus booster in his left deltoid. Med. recs. at Ex. 6, p. 4.

Dr. Thornton's handwritten notes for February 7, 1994 state that, after the DT injection, James was in the car with his mother on a trip to the post office. When his mother was out, he was pale and sweaty. She brought him back to the doctor's office. He was pale, but answered questions. They put his feet up. His blood pressure was okay. His normal sinus rhythm was 96. He was sweaty. They observed James for over thirty minutes. His color gradually returned. His blood pressure was stable. His pulse was slower. He had less distress and sat in the waiting room. Then he went home with his mother. Med. recs. at Ex. 36. James did not return to Dr. Thornton again.

On February 8, 1994, Martin Tulloch, a special needs teacher at Falmouth Public Schools, wrote that he was worried about James' steady stream of maladies. He thought that James was attempting to get attention. Med. recs. at Ex. 13, p. 30.

On February 24, 1994, James was taken to Massachusetts General Hospital Emergency Room (ER) where his mother gave a history that about one week previously [it was actually two and a half weeks previously], James received a tetanus shot, and that he had had developmental delay and seizure two weeks previously. Last week, about fifteen minutes after the tetanus shot, James had a generalized tonic-clonic seizure lasting about two minutes. He did not have incontinence. It was unclear if he had eye rolling. He was very sleepy after the seizure. Over the past month, James had had a decrease in energy and personality changes also. He spoke at age five, and walked late. Now, James was developmentally at the first grade level. Med. recs. at Ex. 7, p. 1.

The Emergency Nursing Flow Sheet, dated February 24, 1994, notes that James' mother stated she noticed a change in his mental status about one month ago. She stated that James was not with it. His mother also stated that James received a tetanus shot about one week previously and then had a possible

seizure. James was alert and ambulatory, but confused as to place, date, and time. Med. recs. at Ex. 7, p. 4.

On March 4, 1994, James was given an MRI, which showed a nonspecific demyelinating process. Med. recs. at Ex. 7, p. 6.

On March 15, 1994, James was taken to Falmouth Hospital where he appeared catatonic and had an elevated bilirubin. He stared at times. The history the mother gave was that he had received tetanus vaccine four weeks previously and had a seizure. Since then, he was not well and was less communicative than before. Med. recs. at Ex. 8, p. 2.

On March 18, 1994, James saw Dr. Hope Brooks, a pediatrician, who recorded that he had a tetanus vaccination on February 7th and a thirty-second seizure within fifteen minutes, and a personality change. He stared all the time. He responded to questions. He has been home from school the past month. Dr. Brooks' impression was a psychiatric problem in the someone mentally retarded. Med. recs. at Ex. 10, p. 3.

On March 23, 1994, James received an EEG at Southeastern Massachusetts Neurologic Associates from Dr. Lee I. Corwin. The EEG was suspicious due to the appearance of diffusely projected sharp and slow activity with hyperventilation. Med. recs. at Ex. 9, p. 1.

On April 6, 1994, a pediatric neurologist at Massachusetts General Hospital recorded that James had a lifelong history of severe-moderate developmental delay. On February 7, 1994, he had a tetanus shot. Fifteen minutes later, while in the car, he apparently had a convulsion according to his mother. His arms and body began to jerk, he turned pale, his lips were blue. James responded to his name, but seemed very tired afterwards. He and his mother returned to the doctor's office where James was allowed to lie down until his color returned.

Prior to this episode, there was a similar "convulsion" the prior year at school. James' swimming coach noticed that James had not returned to the pool after going to the lockers. He found James standing in the locker room, pale, cyanotic, disoriented. Other than that, there have been no other seizure-like episodes. Until the episode two months ago, James was in his baseline state. Since then, his mother noted that he has been very withdrawn, quiet and stiff. He no longer smiles, is unmotivated, sits around and stares all day. Before, James was on the Special Olympics swim team and a hard worker at school. In addition to his stiffness, James had intermittent diaphoresis[(2)] and pupil dilation which his mother first noticed on the day of his tetanus vaccine.

James had a newly-developed acne-like rash on his chest and back which his mother stated developed over the past two months. Two months ago, James' brother moved in with his mother and James at about the time of the "convulsion." The family history is suggestive of depression. At one to two months of age, James developed a food intolerance with diarrhea and vomiting. He did not gain weight until he was six months of age. He has been developmentally delayed since he was a baby. He did not talk until he was six years old. He walked late. He did not sit or roll at appropriate times. James was working on learning life skills. He cannot read or write, and has trouble talking.

James' father had four hospitalizations for depression and alcoholism. His paternal grandmother had a nervous breakdown. On examination, James had prominent hypokinesia (lessened motion), which raised the possibility of basal ganglia disease or frontal lobe disease. The impression was possible kinetic autism or catatonia. Med. recs. at Ex. 7, pp. 8-13.

On April 11, 1994, James was referred by Massachusetts General Hospital Ambulatory Care Division to a pediatric psychiatrist who noted that James had increasing catatonia, thought disorder, and inappropriate behavior. He was sweaty and tremulous. His mother saw a decline in James' functioning in the past two months. Med. recs. at Ex. 7, p. 8.

On April 24, 1994, according to a student profile of an individual educational plan, James had nearly constant upper body rigidity. He was unwilling to tilt or turn his head, relax his shoulders or arms, or bend at the waist although all these move were possible and seemed not to be painful. Med. recs. at Ex. 13, p. 32.

On April 27, 1994, Dr. Thornton's nurse spoke with Shirley Callihan at the Falmouth High School regarding James' tetanus shot. James supposedly had convulsions. His mother told the school nurse that he had convulsions from the shot and has not been the same since. Med. recs. at Ex. 36.

On June 7, 1994, at the Thorne Clinic, the presenting problems listed were that James received a tetanus booster In February and had a very severe reaction (convulsion). He had gone from an active motivated child to being withdrawn, walking stiffly and being physically rigid. A possible contributing factor was that James' brother Michael had just arrived from the biological father in Colorado. Michael was on probation for drug-related problems. Massachusetts General was uncertain if James had reacted to the tetanus shot or his problem was psychological in origin. James' mother finally called on September 23rd to report that things were much better with both her and James. She felt on a scale of one to ten that they were at an eight. Med. recs. at Ex. 11, pp. 2-5.

On June 14, 1994, Dr. C.E. Thornton filled out a Vaccine Adverse Event Reporting System (VAERS) form, stating that the onset of James' adverse event was February 7, 1994. James was given the diphtheria tetanus booster and his mother then brought him to the post office. He remained in the car, pale and sweaty. His mother brought him back to the doctor's office, and Dr. Thornton saw James. He was pale and answered questions. He was put on the examining table. His blood pressure was okay, his pulse normal, his sinus rhythm 96. They elevated his feet and observed him for thirty minutes. James' color improved and he sat in the waiting room. He went home with his mother. No seizures were noted. Med. recs. at Ex. 6, p. 5.

On June 30, 1994, James went to the Thorne Clinic. He was significantly improved since his last visit. He was smiling, both spontaneously and in response to the doctor's joke. He responded to the majority of questions with yes or no. James initiated some motor action spontaneously. Med. recs. at Ex. 11, p. 14.

On July 1, 1994, Janet Connolly, a therapist, conferred with James' special education teacher, Marty Tulloch, who said he felt that James' symptoms were psychosomatic since they coincided with the return of his brother to live with James and his mother. Prior to the tetanus vaccination, Mr. Tulloch said James was very impaired with a severe language disorder. Med. recs. at Ex. 11, p. 18.

On October 23, 1995, James saw Dr. Edward M. Kaye, a pediatric neurologist at the New England Medical Center. In his letter to Dr. Christina Demopoulos, a psychiatrist at Massachusetts General Hospital, Dr. Kaye states that in his past medical history, James has a longstanding difficulty with cognition and development. His overall development had always been considered significantly delayed. He was delayed in sitting, crawling, and walking. Mrs. Bass did not remember the exact time for these particular motor milestones. He always has been described as having significant problems with communication, especially with expressive language. He has been in a special needs program since early school age. He was described as somewhat of a loner. He was also described as someone who could

never show his feelings. He has never been noticed to cry and at no time had he ever expressed pain. Med. recs. at Ex. 35, pp. 38-39.

Dr. Kaye noted that James' father had had a couple of episodes of nervous breakdowns, and that his paternal grandmother had some psychiatric history. James' IQ was tested in 1995 and it was 53 (full scale). Previous testing in September 1991 also showed a full scale IQ of 53, compared to a full scale IQ of 48 in June 1993. Speech and language progress from August 1995 showed some improvement over the prior two months. Med. recs. at Ex. 35, p. 39.

On testing, Dr. Kaye noted no definite spasticity or rigidity. Dr. Kaye was somewhat leery of attributing all of James' recent problems to a toxic encephalopathy related to the tetanus vaccination. He wrote, "This would have to be considered a very unusual complication to the tetanus and also I would not expect to see an encephalopathy beginning within 15 minutes after receiving the injection without any other hard neurologic findings." Dr. Kaye concluded that James' condition may also represent a psychiatric illness on top of stable mental retardation. Med. recs. at Ex. 35, p. 40.

On February 1, 1996, James had his second MRI which showed increased signal within the periventricular white matter posteriorly likely on the basis of a demyelinating or congenital etiology. P. Ex. 54.

TESTIMONY

Mrs. Joellen Bass testified first for petitioner. She has three children, of whom James is the middle child. Only James lives with her. Michael, the youngest, lives in Colorado with his father. He lived with her February 5, 1994. Mrs. Bass testified that Michael and James get along. Michael left at the end of last summer. James and Michael have two different personalities. James came to live with her in 1993. He had lived in Colorado for a couple of years before that.

When James received the tetanus vaccination, Dr. Clarence Thornton, his pediatrician, had him wait a few minutes. They then left the doctor's office to go to the post office to get mail from a box. In the car, James was very stiff. He leaned back and had a grey color; his lips were purple. He was having a seizure. She has seen seizures before. She called James' name and he came out of it.

She took James back to Dr. Thornton who laid him on a bench and checked his vital signs. James regained his color. Dr. Thornton said it was a normal reaction to the tetanus vaccination. James was able to walk. She told Dr. Thornton that James had had a seizure. He said this was a normal reaction to the tetanus shot.

James was not interested in anything. He would not listen to the radio or watch children playing, as he used to before the vaccination. He did not have a good appetite and gradually lost weight, unlike his eating habits before the vaccination.

She took James to the Falmouth Hospital Emergency Room (ER), but they would not look at him. They would not test him. She told them what happened after the tetanus shot. She received a bill for treating yellow jaundice. She thought James was dying. He lost control of his bowel and bladder. She decided not to take him back to Dr. Thornton after the tetanus vaccination.[(3)] James had not been sick previously, so she never took him to a doctor before Dr. Thornton.

She learned that James had communication problems. His IQ scores are unfair because there was no proper way to test him. When a picture communication system tested him, James had better IQ scores. James did not speak until he was five years old. He spoke more once he was in school. He was

physically fine. Mentally, his thinking was fine.

Mrs. Bass explained James' experience at the pool as his having had the flu that day.

Mrs. Bass' ex-husband had a couple of nervous breakdowns. Her ex-husband's mother had a nervous breakdown when her daughter died.

James was delayed in his early years. He had a hard time adjusting to formulas and would vomit and have diarrhea. For his first six months, he was very sick. She put him on regular milk. James never cried when he was older.

Mrs. Bass testified that James had not been catatonic before February 7, 1994. He was never a real communicator, but after the vaccination, he had to be prompted. He did not have mild jaundice, even though the record includes it. James underwent a complete personality change. He went from being outgoing and able to show his feelings to someone who could not express himself. He did not show interest in what he was interested in previously, except he kept his interest in music.

James has rhythm skills and plays the drums. She got him drum lessons after the vaccination. Before the vaccination, James was a good dancer. He lost his dancing skills after the vaccination. He never had a fine hand tremor before the vaccination. His concentration was radically reduced. Before the vaccination, he used to work on lawn mowers.

James' stepmother told her that James would sit and stare for an hour at a time, unresponsively, before he came to live with Mrs. Bass. When Michael returned to Colorado in the fall of 1996, James' behavior did not change.

After the DT vaccination on February 7, 1994, James was groggy and tired. He was the same on February 8, 1994. He did not show any interest in doing things. She does not remember if James went to school that day. She kept him home on March 4, 1994. He had gotten worse, but that was the first day she removed him from school. James appeared near death: pale, not eating, nonreactive. He was urinating in his pants before they went to the ER at Massachusetts General Hospital. His eyes were rolling when he had his seizure and he was sweating bullets.

Mrs. Bass had a car accident in high school and had a convulsion after she had her daughter, about four years later. She was worried about stress when Michael came. The medical history that refers to James' severe recurrent depression refers to his not being able to communicate. He had staring behaviors when he lived in Colorado.

Mrs. Bass testified that James has never been the same since he had the TD. He improved in certain areas, but needs constant prompting. He cannot be alone. He is still in high school, with one more year to go. Mrs. Bass disagrees with the records that say that, on September 23, 1994, James was much better. She also disagrees with the record that says he did not have a clinical loss of skills since 1992. Before the vaccination, James did thinks without being asked. When confronted with the notation for December 1, 1993 [Ex. 35, p. 14], that James needed strong prompting to take off his jacket, wash his hands, etc., she did not have an explanation for it.

Melissa J. Hergt testified next for petitioner. Mrs. Bass and James lived downstairs from her in 1994. They moved out last year. After James came from Colorado, Mrs. Hergt saw him every day out in the yard with her children.

James had a learning disability. He was very outgoing, happy, athletic, and talking all the time. He carried on a normal conversation concerning what he did at school or with his mother. Mrs. Hergt is a CNA home health aide. She works in a nursing home. She has not worked with the mentally retarded.

James changed, but Mrs. Hergt does not recall the date. The first time she noticed the change, James was returning with his mother in the car, and stared off into space. He would not get out of the car and would not speak. Mrs. Hergt asked Mrs. Bass what was wrong and Mrs. Bass said it was the shot.

James held himself rigidly, his shoulders up to his ears. He would not move his arms, would not swallow, and would sweat a lot. She never saw him return to his pre-vaccination state. Michael seemed to get along with his mother and brother.

Dr. John Tilelli testified next for petitioner. He is a pediatrician and involved in critical care and obstetrics. His opinion was that the tetanus shot led to demyelination. The medical records do not say that James had an encephalopathy within three days of vaccination. But he had encephalopathy after the shot because his brain was injured. His MRI shows demyelination and his EEG shows organic brain injury. Demyelinating injuries are subtle and can affect tone, coordination, and affect.

Dr. Tilelli saw James that day. He had an arresting central tremor suggesting Parkinsonism. He had a flat affect, suggesting mood disorder. Dr. Tilelli admitted that James' onset right after the DT vaccination was hard to understand. He does not attribute James' speech delay to the tetanus vaccine. Dr. Tilelli does not know what to make of the staring episodes before James received the DT vaccine. It was not clear to Dr. Tilelli that James ever had a seizure.

James' demyelinating process is chronic. Therefore, this is not an acute encephalopathy. His being pale and having blue lips after the DT vaccination are not signs of an acute encephalopathy. James did not have any frank neurologic abnormalities after the tetanus vaccination. Dr. Tilelli could not say that the MRI reflected James' brain post-vaccination versus a congenital condition.

Dr. Tilelli testified that James had a static brain condition before the DT vaccination. He cannot quantify what aggravation James had after the vaccination. He also does not know the etiology of James' prior condition. James had significant problems in expressive language prior to the DT vaccination. James did not have a quantifiable change in his IQ after the vaccination. He had similar speech handicaps before the vaccination.

Dr. Jay E. Selman testified for respondent. He stated that James did not have chronic encephalopathy after the vaccination. The exact nature of his acute episode post-vaccination is unclear. There were other facts going on: the return of his brother Michael, the problems pre-existing the vaccination. James returned to baseline within seven months. He did not have any significant change in his psychometric testing.

Dr. Selman stated that a tetanus vaccinal encephalopathy is extremely rare, one case in a million. There was no significant change between James' two MRIs, in 1994 and 1996. Similarly, there was no significant difference between his two EEGs, in 1994 and 1996. If James had experienced an acute process, he would have expected a significant evolution in his symptoms.

James was significantly impaired at an early stage of his life. Catatonia is an unusual response to encephalopathy. It is extremely rare. Catatonia is life-threatening and one is always hospitalized immediately. Someone with encephalopathy would have more constant symptoms and not fluctuate dramatically as James did. His moment to moment fluctuates indicate a non-neurological, that is

psychiatric, basis. He did not know if James had a seizure on February 7, 1994.

DISCUSSION

The history that Mrs. Bass gave at Massachusetts General Hospital ER, both to the doctor and separately to the nurse, was that James' onset of being "not with it" (of mental change) preceded his DT vaccination. She got the date of vaccination wrong (thinking it was the prior week), but in her mind, James' mental change preceded it. The court must assume that if James' sudden mental change had been subsequent to his DT vaccination, Mrs. Bass would have gotten the sequence correct, even if she did not know the exact week of vaccination.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1968); Burns v. Secretary of HHS, 3 F.3d 415 (Fed. Cir. 1993); Estate of Arrowood v. Secretary of HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary of HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment. Cucuras v. Secretary of HHS, 993 F.2d 1525, 1528 (Ct. Cl. 1993):

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical records.

Although Mrs. Bass also told the doctor at Massachusetts General Hospital that James had had a seizure after the DT vaccination, there is little except her own word to support this. Dr. Thornton specifically wrote in his notes and in the VAERS report that James did not have a seizure. In any event, it is apparent that if James is prone to seizing, he manifested a seizure before he received the DT vaccination when he was in the swimming pool locker room and his coach found him. Mrs. Bass says now that James had the flu. In the medical records, however, she was more inclined to link that to a seizure.

Whether James had encephalopathy after the DT vaccination is more easily determined since Mrs. Bass brought James immediately back to Dr. Thornton after the DT vaccination and the visit to the post office. Dr. Thornton had James lie down for half an hour and watched him. It is inconceivable that James would have been encephalopathic in Dr. Thornton's office and Dr. Thornton, though observing James, failed to observe it. Dr. Thornton checked all of James' vital signs. Nothing in his notes or his affidavit suggests that James had a post-vaccinal encephalopathy.

Mrs. Bass and Melissa Hergt insist that James changed radically after the DT vaccination. James may have changed his behavior, a change that Martin Tulloch commented on after some period of watching James in South Falmouth High School in his notation a day after the vaccination (February 8th). That James has had psychological problems for years as well as retardation is apparent from the medical records.

Mrs. Bass testified that before James came back from Colorado, where he had been living with his biological father and stepmother, to live with Mrs. Bass, James' stepmother telephoned Mrs. Bass to alert her to James' staring spells. James' "catatonia" predated his return to Massachusetts as well as his receipt of DT vaccine.

It may very well be that James was faint, pale, and sweaty after his receipt of DT vaccine. But those are

not necessarily symptoms of either a seizure or encephalopathy. It begs credulity to ascribe the onset of a severe neurological condition within Table time of the DT vaccination in an individual who had been manifesting staring and extreme behavior both with his other family in Colorado and in his new school in Massachusetts to the degree that one of the teachers would write his concern about it.

Dr. Tilelli, petitioner's expert witness, was hardly supportive of petitioner's case. He testified that James was ill with significant speech problems before the vaccination. He could not attribute the demyelination manifested on MRI to James' brain post-vaccination because it could have manifested a congenital condition. He did not think that James had an acute encephalopathy after the vaccination and could not explain how the symptoms of which Mrs. Bass testified could be attributable to the vaccination. In addition, Dr. Tilelli could not describe any significant aggravation of James' condition after the vaccination compared to his condition before the vaccination.

All the medical records, psychological testing, and notes from Martin Tulloch indicate that James was the same after the DT vaccination in terms of ability as he was before. It is difficult to conclude significant aggravation without the requisite "substantial deterioration" the statute requires. 42 U.S.C. §300aa-33(4).

The court holds that petitioner has failed to satisfy her burden of proof that James had the onset of encephalopathy or significant aggravation of his pre-existing encephalopathy within Table time of the DT vaccination.

CONCLUSION

This petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix J, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman

Special Master

1. The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. § 300aa-1 et seq. (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.

2. Perspiration, especially profuse perspiration. Dorland's, supra, at 463.

3. The records show that the Falmouth Hospital ER visit of March 15, 1994 was for treating jaundice. This occurred after the visit to the Massachusetts General Hospital ER on February 24, 1994.