

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 08-160V

(Filed: October 20, 2009)

CHAD EMKEY, by)	
FRANK EMKEY and MAILENE EMKEY)	
)	TO BE PUBLISHED
Petitioners,)	
)	Statute of limitations; <u>Markovich</u> ;
v.)	Autism Spectrum Disorder;
)	Significant Aggravation Claim
SECRETARY OF)	
HEALTH AND HUMAN SERVICES,)	
)	
Respondent.)	

Andrew D. Downing, Tulsa, OK, for Petitioners.

Lynn E. Ricciardella, United States Department of Justice, Washington, D.C., for Respondent.

ORDER GRANTING IN PART AND DENYING IN PART RESPONDENT'S MOTION TO DISMISS¹

LORD, Special Master.

I. INTRODUCTION

Mr. and Mrs. Emkey allege that vaccinations caused their son, Chad, to develop autism. The issue presented is whether the Petition was filed more than 36 months after the first symptom of Chad's autism disorder. Chad's father, Frank Emkey, states that there was no sign or symptom of Chad's autism until he reached four years of age, following a vaccination. Chad's medical records indicate, however, that Chad was slow to speak and that his parents noticed his speech delay at around two years of age. There are several other signs of developmental delay in

¹ As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id.

the record, even before Chad reached age two.² These include late walking, late development of fine motor skills, late babbling, as well as late expressive and receptive language skills. Pet'r Ex. 3 at 135, 137.

The record contains medical literature as well as testimony admitted in the Omnibus Autism Proceeding (OAP) showing that speech delay is one symptom -- if not, indeed, the most prominent symptom -- of autism in children between the ages of one and three. There is no medical evidence in the record to the contrary. The abundance and consistency of the medical evidence leave no doubt that the medical community would recognize speech delay as an early symptom in a child subsequently diagnosed with autism.

The special master must dismiss as untimely the claim that Chad's autism was caused by vaccines administered in 2003 in light of Chad's medical history, the reliable evidence that speech delay is recognized as an early symptom of autistic disorders, and the binding precedent concerning application of the statute of limitations in Vaccine Act proceedings. The claim that Chad's condition was significantly aggravated by vaccines he received in 2006 is not dismissed at this time.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. The Petition

On March 7, 2008, Chad Emkey, by his parents Frank B. and Mailene Emkey (hereinafter "Petitioners"), filed a Short-Form Autism Petition (hereinafter "Petition") for Vaccine Compensation under the National Childhood Vaccine Injury Act (hereinafter "Vaccine Act" or the "Act") pursuant to Autism General Order #1, which adopted the Master Autism Petition for Vaccine Compensation.³ Short-Form Autism Petition for Vaccine Compensation (hereinafter Pet.) at 1.⁴ Petitioners alleged that Chad developed autism as a result of vaccinations he received

² Medical records "warrant consideration as trustworthy evidence." Curcuras v. Sec'y of Dep't of Health and Human Services, 993 F.2d 1525, 1528 (Fed. Cir. 1993). Moreover, because medical records are contemporaneous documentary evidence, conflicting oral testimony "deserves little weight." Id. (citing United States v. United States Gypsum Co., 333 U.S. 364, 396, 68 S.Ct. 525, 92 L.Ed. 746 (1948)).

³ The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §300aa of the Vaccine Act.

⁴ By electing to file a Short-Form Autism Petition for Vaccine Compensation Petitioners alleged that

[a]s a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the vaccinee in question has developed a

on February 5, 2003, and again on May 25, 2006, including the measles/mumps/rubella (MMR) and polio (IPV) vaccines. Statement Regarding Onset (hereinafter “Statement”) at 1; Petitioners’ Exhibit 2 (hereinafter “Pet’r Ex.”) at 53.

B. The Medical Record

Chad was born on January 24, 2002, at the Franklin Square Hospital Center in Baltimore, Maryland after a full-term pregnancy. Pet’r Ex. 1 at 1. According to the medical records, Chad did not descend normally through the birth canal. Umbilical cord compression and heart decelerations were noted and an urgent Cesarean section was required. See Pet’r Ex. 6, part 2 at 240-242 (progress notes from Franklin Square Hospital Center at pages 23-25 of 55 of the filing). Chad required resuscitation at birth. See Pet’r Ex. 1 at 14 (progress notes from Franklin Square Hospital Center at page 14 of the filing). He was not breathing, was characterized as “floppy,” and “[t]hick meconium” had to be suctioned from his stomach. Pet’r Ex. 1 at 3 (medical records from Franklin Square Hospital, p. 5 of 56); Pet’r Ex. 1 at 14.⁵

His APGAR scores were four at one minute and nine at five minutes. Id. at 12.⁶ He

neurodevelopmental disorder, consisting of an Autism Spectrum Disorder or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the “thimerosal” ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza Type B (HIB) vaccinations; or by some combination of the two. . . .

The petition is being filed within three years after the first symptom of the disorder, or within three years after the first symptom a vaccine-caused significant aggravation of the disorder. (If the vaccine-related death is alleged, the petition is being filed within two years after the date of death and no later than 48 months after onset of the injury from which death resulted.)

Autism General Order #1 filed July 3, 2002, Exhibit A, Master Autism Petition for Vaccine Compensation at 2.

⁵ Neonatal resuscitation is performed to prevent “the morbidity and mortality associated with hypoxic-ischemic tissue (brain, heart, kidney) injury and to reestablish adequate spontaneous respiration and cardiac output.” Nelson Textbook of Pediatrics 723 (Robert Kliegman, M.D., et al. eds., 18th ed. 2007). Meconium is a dark, viscous material that is normally passed within the first 48 hours of life. Nelson at 1521. Meconium staining of the amniotic fluid may be an indication of fetal stress and may require emergency medical attention. Nelson at 725-26.

⁶ An APGAR score is “a numerical expression of the condition of a newborn infant, usually determined at 60 seconds after birth, being the sum of points gained on assessment of the heart rate, respiratory effort, muscle tone, respiratory effort, muscle tone, reflex irritability, and color.” Dorland’s

weighed seven pounds, 15 ounces and measured 21 inches. Id. at 3. On January 25, 2002, at one day old, Chad was diagnosed with “O/A incompatibility” with “elevated bili[rubin]” and prescribed phototherapy. Pet’r Ex. 1 at 11.⁷ Phototherapy was discontinued the next day. Id. at 7. On January 28, 2002, Chad received his first Hepatitis B vaccination and was discharged from the hospital. Pet’r Ex. 2 at 53. At the time of his discharge, Chad was described as jaundiced, with a decreasing bilirubin count.

On March 1, 2002, Chad received his second Hepatitis B (Hep B) vaccination. Pet’r Ex. 2 at 53. On March 25, 2002, Chad received his first diphtheria-tetanus-acellular-pertussis (DTaP) vaccination. Id. He received an inactivated polio vaccination (IPV) and a Hemophilus influenza vaccination (Hib) on March 28, 2002. On May 29, 2002, Chad received his second IPV, Hib and DTaP vaccinations. Id. He received his third Hep B, Hib and DTaP vaccinations on July 31, 2002. Id. Chad received multiple childhood vaccinations during 2003, including his first measles-mumps-rubella vaccination (MMR) and pneumococcal conjugate (PCV) vaccinations. Id. After his vaccinations in 2003, Chad did not receive any vaccinations until May 25, 2006, when he received MMR, IPV, Hib and DTaP vaccinations. Id.

Chad received routine pediatric medical care from Dr. Don J. Alfonso of Ardent Family Care in Florida. There is a dearth of records concerning Chad’s early development until September 29, 2006, when he was diagnosed with an autism spectrum disorder based on a Neurological Assessment at the University of Florida Developmental Pediatric Center in Jacksonville, Florida. Pet’r Ex. 3 at 140. The Neurodevelopmental Assessment (hereinafter “Assessment”) by David O. Childers, Jr., M.D., was performed at the request of Chad’s parents and Dr. Alfonso, due to concerns about Chad’s language deficits. Id. at 133.

The Assessment stated that, “Initial concerns regarding Chad’s development began at ‘the age of 2 years old, he was not talking much.’” Id. at 135. Other developmental delays dating back two or more years are recorded in the Assessment, including delayed fine motor skills (using spoon, fork, scribbling, and toileting); “Expressive Language” (babbling, saying mama/dada, reaching for wants, index finger pointing) id. at 135; and “Receptive Language” (reciprocal smiling, waving bye-bye, following gestures, identifying body parts, following two-step commands, localizing his mother, understanding “no,” and following ungestured commands). Pet. Ex. 3 at 137.⁸ The historical information recorded in the Assessment was

Illustrated Medical Dictionary 1670 (30th ed. 2003).

⁷ Chad was diagnosed with hyperbilirubinemia on January 10, 2002. Pet’r Ex. 1 at 10. Hyperbilirubinemia is a common neonatal condition caused by excessive bilirubin, which may lead to jaundice. Dorland’s Illustrated Medical Dictionary 879 (30th ed. 2003).

⁸ The Assessment also reports that Chad, as an infant, was “especially quiet and good.” Id. at 135. Some children who are eventually diagnosed as autistic are reported to have been exceptionally quiet babies. See, e.g., Chris Plauche Johnson, “Recognition of Autism Before Age 2 Years,” 28(3) Pediatrics in Review 90 (2008) (“Some infants later diagnosed with autism are unusually quiet and make

based on the report of Chad's mother. Pet'r Ex. 3 at 140 ("This diagnosis is based on both the developmental history provided by Mrs. Emkey and the neurodevelopmental assessment of Chad which were consistent with each other.")

On June 5, 2007, Chad was evaluated at Florida Hospital "for concerns over speech and language development." Pet'r Ex. 3 at 130. That evaluation noted that Chad's father reported: "Chad was not one of those children who developed language and then appeared to 'lose it'. . . Chad has historically been slow to speak." *Id.*

Chad's father, in an Affidavit (hereinafter "Affidavit") submitted August 5, 2008, stated that Chad developed "at what appeared to be a normal rate up through his second birthday," and had no developmental delays at that time. Pet'r Ex. 12 at 1, ¶4 (Emkey Aff.). The Affidavit is silent as to Chad's development between his second and fourth years, but states that Mr. Emkey noticed a marked change in Chad's development after his immunizations in May 2006 (when he was age four and one-half years old) "with delays and an actual digression [*sic*] in his acquired language." *Id.*, ¶5.⁹

C. Proceedings Regarding Timeliness of the Petition

On March 20, 2008, the special master then assigned ordered Petitioners to file the medical records required by 42 U.S.C. §300aa-11(c)(2). Order, March 20, 2008. Petitioners also were notified of the potential applicability of the statute of limitations and that the Office of Special Masters (OSM) has no authority to compensate a case unless it is timely filed. *Id.* The special master instructed Petitioners to provide sufficient evidence, through medical records or the statement of a doctor, "to establish the 'first symptom of onset' that is 'objectively recognizable as a sign of a vaccine injury by the medical profession at large,' in order to

few vocalizations.") (Court Exhibit 1002 at 5) (hereinafter "Court Ex."); *see also*, R.L. Schum, Ph.D., "Language Screening in the Pediatric Office Setting," 54 *Pediatr. Clin. of N. Amer.* 428 (2007) (Court Ex. 1001 at 4)(describing "Case 1: the child who has delayed onset of words: The parents might have described this child as a quiet baby who was not fussy or demanding.").

⁹ If Chad has autism, which seems to be undisputed, it is unlikely, according to the medical experts, that the manifestations of his condition first appeared at age four and one-half. Autism generally manifests by the age of 36 months. Pet'r Ex. 7 at 1-2; Resp't Ex. E at 21; Resp't Ex. F at 20. Autism disorders are characterized by developmental problems in three areas: social reciprocity; social communication; and unusual circumscribed interests and repetitive patterns of behavior. "It's the co-occurrence of those three plus the fact that the origin is in early life, which are the distinctive features." Resp't Ex. F at 16 (quoting Dr. Michael Rutter).

Petitioners' contention that Chad's condition was "at least" aggravated by the vaccinations in 2006, *see* Petitioners Response to Respondent's Motion to Dismiss at 6, impliedly concedes that Chad's problems existed before those vaccinations.

demonstrate that Petitioners filed the instant case within 36 months following that ‘first symptom or manifestation of onset.’” Id. (citing and quoting Markovich v. Sec’y of Dep’t of Health and Human Services, 477 F.3d 1353, 1360 (Fed. Cir. 2007)). Petitioners also were required to file, with Chad’s medical records, a statement “clearly” stating when, in Petitioners’ view, the first symptom or manifestation of onset or of the significant aggravation of Chad’s injury occurred. Id.

In their Statement, Petitioners contended that the onset of Chad’s symptoms did not occur “until the 2006 time frame,” after Chad received his final set of vaccinations, when “the family noticed significant differences in Chad’s behavior as compared to that of” other children. Statement at 2. In support of this Statement, Petitioners referred to the DSM-IV criteria for diagnosis of autism. Statement at 2; see also, Pet’r Ex. 7 at 1-2. Petitioners also asserted, as an alternative ground for awarding compensation, that the medical record “warrants at least a finding of aggravation of Chad’s condition.” Id. at 3. In support of this contention, Petitioners stated that his condition was aggravated by the administration of vaccines containing mercury “over the course of his young life, and even in May, 2006,” because he suffers, according to the Statement, from a toxic accumulation of mercury and other heavy metals in his system. Id. at 3; see also Pet’r Ex. 5 (analysis of urinary porphyrins).¹⁰

On September 2, 2008, Respondent filed a Motion to Dismiss (hereinafter “Respondent’s Motion”) alleging that the Petition was filed outside the statutorily prescribed limitations period. Respondent’s Motion to Dismiss (Resp’t Mot.) at 1. The Secretary asserted that the first symptom or manifestation of onset of Chad’s alleged vaccine-related injury occurred no later than June 2003, when he was approximately 18 months old. Resp’t Mot. at 3, 5 note 1. The date of June 2003 was based on a letter, dated April 14, 2008, written by Chad’s pediatrician, Dr. Alfonso, to United Healthcare Children’s Foundation, in which Dr. Alfonso sought assistance for Chad from the Foundation. Dr. Alfonso stated, “This letter is written in behalf of Chad Emkey who was diagnosed with autism spectrum disorder since an early age of 18 months old.” See Pet. Ex. 3 at 32. Based on this letter, the instant Petition would have been filed more than five years after Chad’s diagnosis.¹¹ The Secretary, in the motion to dismiss, also relied on treating physician records from 2006, see supra, which described Chad as historically “‘slow to speak,’” and noted that, according to his parents, “[i]nitial concerns regarding Chad’s development began at ‘the age of two years old, he was not talking much.’” Id. at 3-4. Piecing together the

¹⁰ Because the assertion of “hypersensitivity to heavy metals” is not linked to any injury other than autism, the same trigger for the statute of limitations applies to the allegation of heavy-metal poisoning. See Bono ex rel. Bono v. Sec’y of Dep’t of Health and Human Services, 87 Fed. Cl. 98, 102 (2009).

¹¹ Dr. Alfonso subsequently submitted another letter, dated October 20, 2008, stating that the information he had provided earlier was wrong, that his records did not reflect that Chad had autism spectrum disorder at the age of 18 months, and that “this statement should have indicated that Chad had been diagnosed 18 months prior to the time of the [first] letter,” which would have been October 2006, less than two years before the Petition was filed. See Pet’r Ex. 13 at 1; infra at p. 16.

chronology from the treatment records, the Secretary argued that the first symptom of Chad's autism was apparent no later than 2004, when Chad was two years old, and that the Petition, filed March 7, 2008, therefore was untimely. Id. at 5, note 1. With regard to the claim of aggravation, the Secretary maintained that there was no medical evidence linking a marked deterioration in Chad's condition after May 25, 2006, to the vaccinations he received on that date. Id. at 6.

Petitioners filed a Response (hereinafter "Response") on October 22, 2008. Petitioners argued that Chad's vaccine injury was not manifested until his autism was diagnosed on September 29, 2006, and that, up until the date of his last round of vaccinations on May 25, 2006, there was no evidence of "even any concern that could be categorized as a 'symptom' of autism." Response at 3-4. Petitioners discounted the evidence of Chad's speech delay documented in the Assessment by his neurodevelopmental pediatrician, arguing that it was irrelevant absent additional symptoms sufficient to support a diagnosis of autism under the criteria set forth in the DSM-IV at 299.00. Id. at 4-6; see Pet'r Ex. 7.

On February 9, 2009, the Secretary filed a Reply to the Petitioners' Response (hereinafter "Reply"), asserting that the records of Dr. Childers, the neurodevelopmental pediatrician who examined Chad in 2006, indicated that Chad's parents were concerned about his language problems in 2004, and that he was noticeably delayed in meeting other developmental milestones. Reply at 3-4. The Secretary reiterated that under existing precedent a first symptom of a disorder triggers the statute of limitations even if it is not recognized at the time as symptomatic of a vaccine-related injury. Id. at 5. With regard to the claim that Chad's autism was aggravated by the vaccinations he received on May 25, 2006, the Secretary again asserted that there was no medical evidence that Chad suffered a substantial deterioration in health following those vaccinations. Id. at 6. According to the Secretary, "there is no reasonable basis to support petitioners' claim of significant aggravation." Id. at 2, 6.

On February 13, 2009, Petitioners filed a Surreply to Respondent's Reply (hereinafter "Surreply") asserting that the pertinent question is not when the first symptom of Chad's autism occurred, but when the first event occurred that is objectively recognizable by the medical profession at large as a sign of a vaccine injury. Surreply at 2, citing Markovich. Regarding the aggravation claim, the Petitioners stated that there "is no timeliness issue" because petitioners' allegations must be accepted at this stage of the proceedings, and they must be afforded the right to provide evidentiary support for their claims at a later date. Surreply at 3, citing Jones v. Sec'y of Dep't of Health and Human Services, 2008 WL 2156746 *9 (Fed. Cl. April 30, 2008).

On July 8, 2009, the undersigned special master issued an Order directing the parties, if they so chose, to file any additional evidence regarding the timeliness issue on or before Thursday, August 13, 2009.¹² Respondent filed additional evidence on August 3, 2009,

¹² Specifically, the July 8, 2009 Order required the parties to file, if they so chose, any additional expert evidence:

1) supporting their respective positions regarding the event that constitutes the

consisting of medical literature and expert testimony admitted in the OAP. Petitioner did not file any additional evidence and did not seek an extension of time in which to do so.

On September 3, 2009, the special master issued an Order to Show Cause requiring an explanation as to why a decision dismissing the Petition should not be entered. Order, September 3, 2009. Petitioners filed their response one day later. Petitioners' Response To Order To Show Cause filed September 4, 2009 ("Show Cause Response").

In the Show Cause Response, Petitioners asserted that the special master should "rely heavily on the treating physician," specifically on Dr. Alfonso's letter dated October 20, 2008, which stated, "I have nothing in my records or within my knowledge that would support a finding that Chad had autism spectrum disorder at the age of 18 months." Show Cause Response at 1-2. The Petitioners did not mention the contradictory letter by Dr. Alfonso to United Healthcare Children's Foundation, dated April 14, 2008, in which the doctor stated that he was writing on "behalf of Chad Emkey who was diagnosed with autism spectrum disorder since an early age of 18 months old." Pet'r Ex. 3 at 86.

Petitioners declared: "at no time was there any documentation of any concerns or issues that can be used to start the running of the statute of limitations." Show Cause Response at 2. Petitioners did not account for the Assessment by Chad's treating physician, Dr. Childers, dated June 5, 2007, which recorded Chad's history of delayed speech and other developmental delays, or the documentation concerning speech delay by the professionals at Florida Hospital. See e.g. Pet'r Ex. 3 at 130, 135, 140.

Finally, Petitioners contended that, even if their claim that his vaccinations caused the onset of Chad's autism was filed out of time, they still had a viable claim in the alternative for relief based on significant aggravation of Chad's condition by vaccines he received in May 2006, at age four and one-half. Show Cause Response at 2-4. Petitioners asserted that Rule 8(d) of the Federal Rules of Civil Procedure allows claimants to plead in the alternative.

D. Evidence That Delayed Speech Is Recognized in the Medical Community As An Early Symptom Of Autism

The following materials were submitted by Respondent (hereinafter "Respondent" or the

first symptom or manifestation of petitioner's autism spectrum disorder;
and/or

- (2) bearing directly on the question of what events are generally considered by the medical profession to constitute the first symptoms or manifestations of onset of an autism spectrum disorder. See 42 U.S.C. 300aa-16(a)(2).

(Emphasis in original.)

“Secretary”) in response to the Order dated July 8, 2009, to prove that language and speech delays are among the first signs of an autism disorder generally recognized in the medical community. Petitioners submitted no such evidence in response to the July 8, 2009 Order. See infra at p. 13, and note 16.

1. Rhiannon J. Luyster et al., “Language Assessment and Development in Toddlers with Autism Spectrum Disorders,” 38 J. Autism Dev. Disord. 1426 (2008) (Resp’t Ex. A at 2):

Delays and deficits in language acquisition are among the key diagnostic criteria for autism spectrum disorders (American Psychiatric Association 1994), and the absence of first words and phrases is the foremost reason reported by caregivers of children with ASD for their initial concern about their child’s development (DeGiacomo and Fombonne 1998; Wetherby et al. 2004).

2. Rebecca J. Landa, “Diagnosis of Autism Spectrum Disorders in the First 3 years of life,” 4(3) Nature Clinical Practice Neur. 138 (March 2008) (Resp’t Ex. B at 3):

Parental concerns that a child has an ASD can arise as early as the first year of life, but they are most likely to arise when a child who is later diagnosed with an ASD is at a mean age of 18 months. Approximately 80% of parents of children with ASDs notice abnormalities in their child by 24 months of age, which usually involve delays in speech and language development

3. Testimony of Dr. Eric Fombonne, Resp’t Ex. D at 50 (see Cedillo v. Sec’y of Dep’t of Health and Human Services, No. 98-916V, 2009 WL 811449, (Fed. Cl. Spec. Mstr. Feb. 12, 2009) (Trial Tr. at 1266A, June 18, 2007) C, regarding “abnormalities in language and communication:¹³

[P]articularly as they present young infants, for instance, often there is language delay. There is no babbling. There can be no babbling in a young infant or the babbling can be very limited. For instance, you could recognize that the amount of babbling is reduced or the quality of the babble is also altered. There would be very little babbling not directed to communicate. It would be self-directed, not used with a communicative intent.

¹³ Transcripts for the OAP may be accessed at the following website: <http://www.uscfc.uscourts.gov/omnibus-autism-proceeding> (last checked on October 19, 2009). The qualifications of the experts whose opinions are cited appear in the records of the OAP.

From the same testimony, id. at 49 (see Cedillo Trial Tr. at 1284):

[O]ne of the first concerns which is often noted by parents is the lack of development of language.

Typically at age 15, 16, 18 months parents become worried because their child is not talking yet, and they can see that other children have started to develop words, many words by then.

4. Testimony of Dr. Max Wiznitzer, Resp't Ex. E at 49 (see Cedillo, Trial Tr. at 1619A) , No. 98-916V, at , describing a "typical timeline" for the progression of children with autism:

This is a pattern that children may follow where in the second year of life the children really don't have well developed imitation. They don't have good language. There's a problem with socialization.

Resp't Ex. E at 55 (Cedillo, Trial Tr. at 1642):

[W]hen we are looking at communicative ability, we look at – not only do we look at what sounds they are making, whether they are making vowel sounds when they are young in infancy, whether they are babbling when they are in the later portion of infancy, and whether they are using words when they are in the second year of life, but also what they are doing with it and how much they are doing with it .

Resp't Ex. E at 56 (Cedillo, Trial Tr. at 1643):

If I have a child who does vocalize, but the vocalization that is present is minimal, it's not as much as I would expect, in other words, the quantity is not as much as I would expect, that's something that raises questions in my mind about what's going on.

Resp't Ex. E at 57 (Cedillo, Trial Tr. at 1644):

[R]ealizing that these early features may not be as flagrant as the autistic features that we will see at age 2 or 3 years, but they will be different than what we would normally expect for the behavior of an infant or a young child in the second year of life

5. Testimony of Sir Michael L. Rutter, M.D. (hereinafter "Dr. Rutter"): Resp't Ex. E at 25 (see King v. Sec'y of Dep't of Health and Human Services, No 03-583V) (Tr. 3259):

a child's parents typically begin recognizing developmental problems in a child who turns out to be autistic at around 18 to 24 months.

Resp't Ex. E at. 26 (see King v. Sec'y of Dep't of Health and Human Services, No 03-583V) (Tr. 3260):

"The communication problems and the lack of social reciprocity are often the first things to be picked up . . . They are picking up the social and communicative abnormalities as a rule.

The special master also notes the following article, which has been entered into the record:

6. Chris Plauche Johnson, "Recognition of Autism Before Age Years," *Pediatrics in Review* (2008) at 89 (Court Ex. 1002 at 4):

"Historically, delays and deviances in language development have been the most common presenting signs in children later diagnosed with autism."¹⁴

III. DISCUSSION

A. The Claim That Chad's Autism Was Originally Caused by Vaccines Is Untimely.

1. Applicable Law Regarding the Statute of Limitations

In pertinent part, Section 300aa-16(a)(2) of the Vaccine Act states: [i]n the case of . . .

- (2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no

¹⁴ Information concerning language delay as an early of autism is widely available to the public. See National Institute of Child Health and Human Development (NICHD) website, "Autism Overview: When do people usually show signs of autism?" <http://www.nichd.nih.gov/publications/pubs/autism/overview/showSigns.cfm> (last checked Oct. 19, 2009). The NICHD states that, "A number of the behavioral symptoms of autism are observable by 18 months of age," including problems with language. "[I]n many cases, a delay in the child's starting to speak around age two bring problems to parents' attention, even though other, less noticeable signs may be present at an earlier age." Id. (Footnotes omitted). See also, <http://cdc.gov/ncbddd/autism/facts/html> (last checked October 20, 2009).

petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.

The statute of limitations under the Vaccine Act must be “strictly and narrowly construed” because it is a condition of the waiver of the government’s sovereign immunity. Markovich, 477 F.3d at 1360 (quoting Brice v. Sec’y of Dep’t of Health and Human Services, 240 F.3d 1367, 1370 (Fed. Cir. 2001) (“Brice I”). Under the Act, the statute of limitations may be triggered by a “first symptom” or “manifestation of onset.” A symptom “may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury.” Markovich at 1357. “[A]ny observable ‘symptom or manifestation’ may be the first evidence of injury.” Markovich at 1358 (quoting Shalala v. Whitecotton, 514 U.S. 268, 274 (1995)) (emphasis in original). As the court stated in Markovich at 1359 (citing Brice v. Sec’y of Dep’t of Health and Human Services, 36 Fed. Cl. 474, 477 (1996)), “Congress intended the limitations period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act.”¹⁵

These binding authorities establish that diagnosis of a disorder allegedly caused by a vaccine is not required to trigger the statute of limitations. See Cloer v. Sec’y of Dep’t of Health and Human Services, 85 Fed. Cl. 141, 144-45 (2008), appeal docketed, No. 2009-5052 (Fed. Cir. Mar. 9, 2009); Lemire v. Sec’y of Dep’t of Health and Human Services, No. 01-0647V, 2008 WL 2490654 (Fed. Cl. Spec. Mstr. June 3, 2008) (holding that recognizable signs of autism occurred well before diagnosis). Even where the medical community would not have been able to diagnose the symptoms as manifesting a particular disorder, the statute of limitations commences “on the date the first symptom or manifestation of onset occurs.” Cloer, 85 Fed. Cl. at 145. “[T]he limitations period begins to run at the first occurrence of a symptom even though an exact diagnosis may be impossible until some future date when more symptoms or medical data are forthcoming.” Cloer, 85 Fed. Cl. at 149 (citing Markovich, 477 F.3d at 1358-59). Further, to trigger the statute of limitations, a symptom or manifestation of an injury need not be accepted by the medical profession at large as an injury linked to a vaccine; it need only be identifiable as a symptom or manifestation of an injury. See Bono ex rel. Bono v. Sec’y of Dep’t of Health and Human Services, 87 Fed. Cl. 98, 102 -03 (2009). Cf. Surreply at 2.

2. Application of the Law to This Case

Based on clear precedent, resolution of the timeliness issue requires only the application

¹⁵ Accord, e.g., Hebert v. Sec’y of Dep’t of Health and Human Services, 66 Fed. Cl. 43, 47, 49 (2005); Wilkerson v. Sec’y of Dep’t of Health and Human Services, 2009 WL 1583527 (2009); Hedrick v. Sec’y of Dep’t of Health and Human Services, 2008 WL 5049439 at * 3 (Fed. Cl. Nov. 3, 2008); Staley v. Sec’y of Dep’t of Health and Human Services, 2007 WL 268779 at * 3-4 (Fed. Cl. 2007).

of established law to the facts in the record. There appears to be no genuine issue of fact regarding recognition by the medical community of speech delay as an early symptom of autism, and no genuine issue of fact as to the content (as opposed to the legal interpretation) of the medical record.

Respondent's submissions of expert evidence focused appropriately on the early symptoms of autistic disorders that are recognized by the medical community. The evidence in the medical literature identified speech delay as one of the first symptoms of autistic disorders. See, e.g., Resp't Ex. A at 2 ("the absence of first words and phrases is the foremost reason reported by caregivers of children with ASD for their initial concern about their child's development"); Resp't Ex. B at 3 ("Approximately 80% of parents of children with ASDs notice abnormalities in their child by 24 months of age, which usually involve delays in speech and language development . . ."); Court Ex. 2 at 4 (Johnson) ("Historically, delays and deviances in language development have been the most common presenting signs in children later diagnosed with autism.")

The expert testimony from the OAP similarly demonstrated that the medical community recognizes language delay as a common early symptom of autism. Dr. Eric Fombonne testified that children who are later diagnosed as autistic present as "young infants" with language delay. Resp't Ex. D at 50 ("There is no babbling. There can be no babbling in a young infant or the babbling can be very limited.") Dr. Fombonne testified further that speech delays "typically" concern parents of autistic children at age "15, 16, 18 months." Id. ("They can see that other children have started to develop words, many words by then.") Dr. Max Wiznitzer echoed the testimony that children who turn out to have autism follow a pattern such that, "in the second year of life," they "don't have good language." Resp't Ex. E at 49. Dr. Wiznitzer's testimony took account of the normal variation in child development but made it clear that, notwithstanding the acknowledged variation, children later diagnosed as autistic typically exhibit impairment of language skills as "an infant or a young child in the second year of life. . . ." Id. at 57. Dr. Rutter similarly opined that "a child's parents typically begin recognizing developmental problems in a child who turns out to be autistic at around 18 to 24 months, when "communication problems and the lack of social reciprocity" are "the first things to be picked up." Resp't Ex. E at 25-26.

A special master may draw conclusions from medical evidence even if medical experts have not commented on it during the particular Vaccine Program proceeding. Cf. Moberly v. Sec'y of Dep't of Health and Human Services, 85 Fed. Cl. 571, 597-98 (2009), appeal docketed, No. 2009-5057 (Fed. Cir. Mar. 17, 2009) ("Court has no trouble concluding that a special master may interpret and apply the conclusions of a medical study introduced into the record by a party, without the guidance of expert witnesses"). This record contains reliable medical evidence that speech delay, in particular, is an "event objectively recognizable as a sign" of an autism spectrum disorder "by the medical profession at large." Markovich, 477 F.3d at 1360. No evidence has been submitted to the contrary.

The special master has examined Chad's records with a view to finding objective evidence of the early symptoms of autism recognized in the medical community. The record is sufficient to persuade the special master that Chad exhibited early symptoms of autism long before age four and one-half. The delays in Chad's motor development and language, as well as the documented reports of Chad's infant behavior, see supra at p. 4, are recognized as early symptoms of autism in children who are later diagnosed, according to the experts in the field.

Most prominently, the medical record reveals that Chad's speech was delayed and that the delay was observed by his parents at about the age of two. Pet'r Ex. 3 at 135. The speech delay (as well as other significant developmental deviations) was reported to Chad's medical providers, in particular, the neurodevelopmental pediatrician who ultimately diagnosed his autism, under circumstances that support the reliability of the Emkeys' report. Id.; see also Curcuras v. Sec'y of Dep't of Health and Human Services, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (noting trustworthiness of medical records created with "proper treatment hanging in the balance."). On this record, the statute of limitations commenced to run, at the latest, on January 24, 2004, when Chad reached the age of two. The claim for relief based on the allegation that Chad's autism was originally caused by his vaccines, filed on March 7, 2008, therefore is out of time.

B. Petitioners Have Not Met Their Burden to Establish That The Claim of Original Causation Was Timely Filed.

1. Petitioners' Burden To Establish Jurisdiction

In their Show Cause Response, Petitioners argued that the special master must accept their allegations as true and construe the facts in the light most favorable to them, citing Rule 12 of the Rules of the Court of Federal Claims. See Show Cause Response at 2, 4. This view of the evidentiary burden is erroneous.

The statute of limitations under the Act is jurisdictional. See, e.g., Brice v. Sec'y of Dep't of Health and Human Services, 358 F.3d 865, 868 (Fed. Cir. 2004) ("Brice II"); Kay v. Sec'y of Dep't of Health and Human Services, 80 Fed. Cl. 601, 603-04 (2008), aff'd per curiam, 298 F. App'x 985 (Fed. Cir. 2008) (unpublished). See generally, John R. Sand & Gravel v. U.S., 552 U.S. 130 (2008), 128 S.Ct. 750,753 (2008) (distinguishing between the treatment of typical limitations defenses and jurisdictional statutes of limitations). As a result, the burden is on Petitioners to establish that their claim is timely. Initially, the party asserting jurisdiction must make a prima facie showing of jurisdictional facts to defeat the motion to dismiss. See, e.g., Reynolds v. Army & Air Force Exch. Serv., 846 F.2d 746, 748 (Fed. Cir. 1988) and cases cited therein (under Tucker Act, plaintiff bears burden of establishing waiver of sovereign immunity). Where there is "a factual attack on jurisdiction, however, the court 'is obliged to look beyond the pleadings and decide for itself those facts, even if in dispute, which are necessary for a determination of [the] jurisdictional merits.'" Raymark Industries, Inc. v. U.S., 15 Cl. Ct. 334, 335 (1988); see also Figueroa v. U.S., 57 Fed. Cl. 488, 492 (2003) ("If, however, the motion

challenges the truth of the jurisdictional facts alleged in the complaint, the court may consider relevant evidence in order to resolve the factual dispute.") (citing Rocovich v. U.S., 933 F.2d 991 (Fed. Cir. 1991)).

In its Motion to Dismiss, Respondent challenged the factual basis for the Petitioners' assertion of jurisdiction, pointing to evidence in the record indicating that the first symptoms of Chad's autistic disorder preceded the filing of Petitioners' claim by more than 36 months. The standards applicable to a motion to dismiss based solely on the pleadings, therefore, no longer applies. Instead, the special master must look beyond the pleadings to determine the facts necessary to establish whether the Petition is timely. See Rocovich, 933 F.2d at 993-94 ("In determining whether a motion to dismiss should be granted, the Claims Court may find it necessary to inquire into jurisdictional facts that are disputed."). In addition, where the movant makes a factual showing challenging the timeliness of a claim, the burden of going forward with the evidence shifts back to the party seeking to establish jurisdiction to show that the claim is within the applicable limitations period. The burden of proof, "i.e., the burden of ultimate persuasion," never shifts. Cf., e.g., Grapevine Imports, Ltd., et al., v. U.S., 71 Fed Cl. 324, 343 (2006) (describing shifting burden of production under a non-jurisdictional statute of limitations). The result is that Petitioners may not rest on their prima facie allegations but must respond with persuasive evidence to counter Respondent's showing that Chad exhibited the first symptoms of autism more than 36 months before the Petition was filed.

To prevail, moreover, Petitioners must establish jurisdiction by a preponderance of the evidence. When a decision on jurisdiction requires consideration of facts beyond those alleged in the pleadings, the "appropriate quantum of the burden that the plaintiff [i.e., the non-moving party] must clear" in order to resist a motion to dismiss "will rest upon such factors as the nature of the proceeding and the type of evidence that the plaintiff is permitted to present." Raymark, 15 Cl. Ct. at 337 (citations omitted). "[T]he limits imposed by the trial judge upon pretrial proceedings will dictate the burden the plaintiff is required to meet." Id. Where proceedings are limited to written materials, the plaintiff's written materials "must make only a prima facie showing of jurisdictional facts." Id. at 338. Where proceedings are not so limited and the court accepts evidence in order to resolve contested factual issues, the plaintiff must then be put to its full burden of proof. Id. In that circumstance, "plaintiff must establish the jurisdictional facts by a preponderance of the evidence, just as [it] would have to do at trial." Id. See Data Disc, Inc. v. Systems Tech. Ass'n, Inc., 557 F.2d 1280, 1285 (9th Cir. 1977).

Petitioners' contention that they need to make only a prima facie showing to establish jurisdiction is incorrect in the context of this proceeding, in which both sides have submitted evidence well beyond the pleadings. See Show Cause Response at 4-5. A full evidentiary hearing has not been held, but there has been no request for such a hearing. Petitioners did not avail themselves of the multiple opportunities to present additional evidence on the timeliness issue. See e.g., Order, Jan. 7, 2009; Order, July 8, 2009; Order to Show Cause, Sept. 3, 2009. Contrary to Petitioners' contention that the special master must accept all of their allegations as

true, in these circumstances Petitioners fairly are held to the burden of demonstrating that jurisdiction exists by a preponderance of the evidence.

2. Petitioners' evidence and arguments are not persuasive.

a. Dr. Alfonso's letters

In the Show Cause Response, Petitioners asserted that their claim that Chad's autism was originally caused by his vaccines was timely filed, based largely upon a statement in the October 20, 2008 letter from Dr. Alfonso. See supra at note 11. The special master does not rely on Dr. Alfonso's statement for several reasons.

- Dr. Alfonso's letters contradict each other; one of his letters says Chad was diagnosed with autism at 18 months, the other says he did not have an autism spectrum disorder at 18 months. Compare Pet'r Ex.3 at 86 with Pet'r Ex. 13. Given this conflict, the special master is not comfortable placing reliance on the statements in either letter.
- Dr. Alfonso's letters concerned the date of Chad's diagnosis, which is not necessarily the operative date for determining the onset of the limitations period, as discussed herein. In the context of the statute of limitations, we focus on the symptoms Chad exhibited, not on whether he had "autism spectrum disorder at 18 months." See Pet'r Ex. 3 at 86. If Dr. Alfonso were to testify, consistent with Petitioners' arguments and the letters, that Chad was not diagnosed with autism at an early age, that testimony would be irrelevant under binding precedent. See Markovich.
- To the extent that Dr. Alfonso's second letter could be interpreted as an opinion that Chad never exhibited early symptoms of autism, that information would conflict with the evidence in the treatment records of the experts on pediatric neurodevelopment who noted that Chad's father reported his speech delay at age two. Dr. Alfonso's "opinion" would not outweigh factual information in the records of Chad's other treating physicians.
- The reported absence of information in Dr. Alfonso's possession concerning Chad's autism, see Pet'r Ex. 13 ("I have nothing in my records or within my knowledge that would support a finding that Chad had autism spectrum disorder at the age of 18 months."), is less probative than the presence of such records in Dr. Childers' possession (records that Dr. Alfonso specifically references as being in his own records as well, see Pet'r Ex. 13), and in the records of other treating professionals. See Pet'r Ex. 3 at 140 (Florida Hospital records noting

Chad's father's report of "historically" slow speech). "Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." Murphy v. Sec'y of Dep't of Health and Human Services, 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992) (unpublished) (citing and quoting Clark v. Sec'y of Dep't of Health and Human Services, No. 90-45V, slip op. at 3, 1991 WL 57051 (Cl. Ct. Spec. Mstr. March 28, 1991)).

- Dr. Alfonso's second letter plainly was prepared for the purpose of this litigation, unlike the letter it purportedly corrected, which apparently was authored by Dr. Alfonso to assist Chad in obtaining financial support. See Pet'r Ex. 13. Specifically, the second letter was prepared only after Respondent, based in part on Dr. Alfonso's first letter, moved to dismiss on limitations grounds. Neither letter was created in the normal course of Chad's treatment, thus neither bears the indicia of enhanced reliability customarily pertaining to the records of a treating physician. See Curcuras, 993 F.2d at 1528 (noting trustworthiness of medical records created with "proper treatment hanging in the balance.")
- Unlike Andreu v. Sec'y of Dep't of Health and Human Services, 569 F.3d 1367 (Fed. Cir. 2009), this is not a case in which a treating physician's opinion is offered to establish whether a vaccine caused an injury. Dr. Alfonso's statements relate not to medical opinion rendered in the absence of definitive factual information, but to historical facts that can be established based on the medical records. Dr. Alfonso's letters present no factual evidence that contradicts the evidence in the records of Chad's other treating physicians that Chad exhibited symptoms of autism by the age of two.
- Even if Dr. Alfonso were to testify in this context, the relevant questions would be (1) what are the early symptoms of autism recognized in the medical community at large; and (2) when did Chad first exhibit those symptoms? On the first question, Dr. Alfonso might agree with the many authorities who are on record stating that speech delay is one of the earliest symptoms, or he might disagree. If he disagreed, his testimony would not overcome the great weight of the evidence cited herein from recognized experts on autism. On the second question, as explained above, whether Dr. Alfonso testified as to a lack of knowledge of Chad's symptoms, or offered an opinion that Chad had no such symptoms, his testimony would not outweigh the clear record evidence

of Chad's speech delay.¹⁶

b. Chad's Pre-school evaluation

Under the teaching of Curcuras, it is significant that the history of Chad's speech delay was reported to Dr. Childers and others whose assistance Petitioners specifically sought because of their expertise in childhood developmental disorders. Petitioners, in contrast, relied on a standard, pre-school evaluation form completed when Chad was age three and one-half. Show Cause Response at 7-8. That form, filled in by a nurse practitioner, noted that Chad had no physical infirmities that would preclude participation "in school activities including physical education." Pet'r Ex. 3 at 75. The form did not address the developmental problems noted elsewhere in Chad's medical records, on which the special master relies.¹⁷

c. Court's exhibits on early symptoms of autism

Petitioners responded specifically to one exhibit of the many that were offered to establish that speech delay is an early symptom of autism. Show Cause Response at 5-6; see Court Ex. 1002: Chris Plauche Johnson, M.D., "Recognition of Autism Before Age 2 Years," 28(3) Pediatrics in Review (2008). This exhibit, an article on the recognition of autism, stated: "Absent or delayed speech has been the most common presenting sign in children who have autism." Court Ex. 1002 at 1. (Johnson article 86). The article recommended that children with delayed speech should be referred to a speech and language pathologist "to evaluate both expressive and receptive language." Id. If the child's receptive language is normal, a 'wait and see' approach may be appropriate. . . ." Id. "If hearing is normal but receptive language is delayed, the [primary care physician] must consider the possibility of autism" Id.

¹⁶ As noted above, Petitioners have not requested an evidentiary hearing. Were they to do so, the special master would have discretion to decide the case on the written record, provided that each party has been afforded a full and fair opportunity to present its case. See 42 U.S.C. § 300aa-12(d)(3)(B)(v); Vaccine Rule 8(b). Accord, e.g., O'Connell v. Sec'y of Dep't of Health and Human Services, 63 Fed. Cl. 49, 57 n. 7 (2004) (affirming the special master's decision not to hold formal hearings); Hovory v. Sec'y of Dep't of Health and Human Services, 38 Fed. Cl. 397, 400-01 (1997) (affirming special master's decision denying petitioners' request for an evidentiary hearing). In this instance, the parties specifically were offered two opportunities to present expert testimony on the early symptoms of autism spectrum disorder: a Court Order issued on July 8, 2009, and the Show Cause Order issued on September 3, 2009. Respondent submitted expert medical evidence, Petitioners did not.

¹⁷ The nurse left blank the boxes indicating problems in Vision, Hearing, Speech/Language, Physical, Social/Behavioral, and Cognitive functions. See Show Cause Response at 8; Pet'r Ex. 3 at 75. The nurse practitioner did note on the page of the exhibit following the one cited by Petitioners that Chad was "not being cooperative" during the examination. Pet'r Ex. 3 at 76. This would be consistent with the behavioral problems that eventually led to his diagnosis. Affidavit at ¶5.

From the quoted passage, Petitioners derived the message that "receptive" language delay is the type of language delay that must be found for a physician to suspect autism. Show Cause Response at 6-7. They asserted that Chad exhibited "no evidence whatsoever" of "receptive" language delay. Id. at 7. Petitioners apparently discounted the evidence in the Assessment by Dr. Childers, which indicated that Chad's receptive language skills were significantly delayed. Pet'r Ex. 3 at 137. Under "Receptive Language History," the Assessment records that Chad was late to engage in reciprocal smiling, wave bye-bye, follow gestures, indicate one body part, follow two-step commands, localize his mother, understand "no," follow ungestured commands, and indicate multiple body parts. Id. In addition to this oversight, Petitioners missed the significance of the expert's opinion. The Johnson article recommended that a child with any speech delay, expressive or receptive, should be evaluated, because speech delay may be an early symptom of an autistic disorder. Depending on the nature of the speech problem, autism may or may not be diagnosed at that time, but the child's development should be monitored regardless. See Court Ex. 1002 at 1 ("a 'wait and see' approach may be appropriate").

Petitioners also misread expert evidence concerning infant behavior as indicative of future autism. The same article quoted above stated: "Some infants later diagnosed with autism are unusually quiet and make few vocalizations." Court Ex. 1002 at 5; see also Court Ex. 1001 at 4. Petitioner did not offer any evidence to dispute this statement. Petitioners asserted instead that the paragraph in which the statement appears "says nothing other than all children are different." Show Cause Response at 6. This is not a fair characterization of the quoted passage. The exhibit pertinently identified a number of speech and behavior patterns exhibited even in infancy that are characteristic of children who are later diagnosed with autism. Id. at 5. See Court Ex. 1002 at 5.

To be certain, every good baby is not destined to develop autism. Infants who make atypical vocalizations may not be autistic, and the same holds true for inconsolable infants who cry for extended periods of time. See Court Ex. 1002 at 5. But the medical community recognizes these behaviors as characteristic of many young children who later are diagnosed with autism. These are therefore the types of behaviors that are useful in deciding when the statute of limitations begins to run.

The underlying flaw in Petitioners' arguments is the apparent misinterpretation of the Federal Circuit's instruction on how to apply the statute of limitations. Petitioners adopt the position that there must be enough evidence in the medical record to make a diagnosis of autism before the statute of limitations can commence. That is not the proper focus of the inquiry. Consistent with the Federal Circuit's decisions concerning onset of an injury in the statute of limitations context, we do not look solely at an initial symptom to determine if, at the time the symptom occurred, a doctor would have diagnosed autism. Instead, we look back from the date of diagnosis to determine when, as a historical matter, a symptom of the injury that we know will eventually be diagnosed as autism first appeared. Then we determine whether the petition was filed within 36 months after the appearance of that first symptom. The statute of limitations begins to run from the date the first symptom or manifestation of autism appeared that would be

recognized by the medical community at large. Markovich, 477 F.3d at 1359, 1360 (“Congress intended the limitations period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act.”)

C. The Significant Aggravation Claim

The Act defines significant aggravation as “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” 42 U.S.C. § 300aa-33(4); see Shalala, 514 U.S. at 272. Under Whitecotton, unless Chad had a “preexisting condition,” Petitioners cannot establish a significant aggravation of his condition under the Act.

Petitioners maintained that Chad had no developmental disorder (much less an autism spectrum disorder) before May 2006 when he was re-vaccinated, or “even any concern” of such a disorder, see Response at 3-4. If the Petitioners’ factual contentions concerning Chad’s condition are true, the vaccinations in May 2006 cannot as a matter of law have resulted in significant aggravation of his disorder, because there would have been no “preexisting condition” to be aggravated. Either Chad had a disorder before he was re-vaccinated in May 2006, or he had no disorder before May 2006, in which case there was no condition to be aggravated.

To overcome this obstacle, Petitioners cited Rule 8(d) of the Federal Rules of Civil Procedure, which permits a party to “set out” alternative claims or defenses, “regardless of consistency.”¹⁸ Petitioners’ analysis is insufficient to save the significant aggravation claim.

Rule 8 of the Federal Rules of Civil Procedure (hereinafter “FRCP Rule 8”) eliminated the doctrine of election of remedies, establishing that litigants may plead alternative and even inconsistent claims. See, e.g., American Int’l Adjustment Co. v. Galvin, 86 F.3d 1455, 1460 (7th Cir. 1996); Kwan v. Schlein, 246 F.R.D. 447, 451 (S.D.N.Y. 2007). This principle extends to inconsistent facts as well as legal theories. Under FRCP Rule 8, consequently, “a factual allegation in one claim should not be construed as an admission against another alternative or inconsistent claim.” In re McCann, 318 B.R. 276, 288 (S.D.N.Y. 2004) (citations omitted).

The rationale for the liberal pleading provisions of FRCP Rule 8 is that, prior to discovery in federal court case, a litigant may not know the facts that will entitle him or her to relief at the end of the day.

[I]n the early stages of litigation, a plaintiff is permitted both to rely on alternative theories of recovery and to incorporate inconsistent facts in separate counts. . . It is often not until discovery that a plaintiff is able to determine which of his claims is sustainable, or if additional facts exist

¹⁸ Rule 8(d) of the Rules of the Court of Federal Claims is identical to the federal rule. Compare Fed. R. Civ. P. 8(d) (hereinafter “FRCP”), and Fed. Cl. R. 8(d) (hereinafter “RCFC”).

which will allow him to pursue multiple claims without contradiction.

Tibor Machine Products, Inc. v. Freudenberg-Nok General Partnership, 967 F. Supp. 1006, 1013 (N.D. Ill. 1997). Accord, e.g., McCann, 318 B.R. at 289 (Rule 8 allows inconsistent positions in the pleadings “[e]specially at the early stages of litigation.”) (citing and quoting Molsbergen v. United States, 757 F.2d 1016, 1019 (9th Cir. 1985)).

Alternative pleading, however, still must conform to the requirements of FRCP Rule 11. Kwan, 246 F.R.D. at 451.¹⁹ “As for the abolition of election of remedies, a pleader may assert contradictory statements of fact only when legitimately in doubt about the facts in question.” American Int’l, 86 F.3d at 1461 (citing FRCP Rule 11); Great Lakes Higher Education Corp. v. Austin Bank of Chicago, 837 F. Supp. 892, 894 (N.D. Ill. 1993) (“[A] pleader may only assert contradictory statements of fact when the pleader legitimately is in doubt about the fact in question.”) (citing FRCP Rule 11). A party is not free to plead any and all facts that might entitle it to relief simply because inconsistency of factual allegations is permissible under Rule 8. A party

‘should not set forth inconsistent, or alternative . . . pleadings unless, after a reasonable inquiry, the pleader legitimately is in doubt about the factual background or legal theories supporting the claims or defenses’

Kwan, 246 F.R.D. at 451-52, citing and quoting 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1285 (3d ed. 2004). Accord, e.g., Ohio Midland, Inc. v. Proctor, No. C2-05-1097, 2006 WL 3793311 at *4 (S.D. Ohio Nov. 28, 2006) (“Plaintiffs may not, under Rule 11 limitations, assert contradictory statements of fact unless Plaintiffs are legitimately in doubt about the facts in question.”) (citing American Int’l); Swormstedt v. Santa Maria Valley RR, 3, No. CV-04-0372 DSF (SHx), 2004 WL 5458405 at * (C.D. Cal. April 13, 2004) (“a pleader may only assert contradictory statements of fact when the pleader legitimately is in doubt about the facts in question”).

Consistent with the reasoning that a party should not be forced to adopt one or another set of inconsistent facts before the party knows what the facts may show, the liberal rules regarding pleading in a federal court apply at the outset of the litigation, before discovery has taken place. A litigant who already knows the pertinent facts at the outset of the case, on the other hand, has no need for discovery to learn them. Such a litigant should plead only facts that are consistent with what he knows – not facts that are inconsistent with what he knows. See Ohio Midland, Inc. 2006 WL at *4. For example, where the contradictory facts “are uniquely within [the litigant’s] knowledge . . . it would be illogical to find that he was in doubt as to what happened.” Gardner v. City of Waukegan, 1999 WL 4100009 (No. 98 C 5372 June 4, 1999 N.D. Ill.) See also Ohio Midland, 2006 WL at *5 (where cause of action alleged depends on the

¹⁹ Rule 11 of the Court of Federal Claims is identical to the FRCP Rule 11. Compare FRCP Rule 11 and RCFC Rule 11.

intention of the pleading party, the pleading party “must know the underlying facts relatively well”).

Chad’s condition was known to Petitioners from the time they filed their claim. Pet’r Ex. 12 at 1; see also Pet. If Chad had a developmental disorder before May 2006 (a necessary prerequisite to establishing a claim based on significant aggravation), then Petitioners knew at the outset of this proceeding that Chad had such a disorder. The record reveals that Petitioners informed Chad’s treating physicians and other providers of his early developmental delays. It thus appears that Petitioners could not have been surprised by the facts concerning Chad’s speech delays and other developmental issues. The rationale supporting permissive pleading of inconsistent facts in the alternative therefore does not apply here.²⁰ Dismissal is appropriate when, as appears in this instance, inconsistent factual allegations were made not because of uncertainty concerning the facts, but to avoid the legal effect of facts that were known from the beginning.²¹

The jurisdictional nature of the statute of limitations under the Vaccine Act heightens the concern that “alternative” pleading in this instance may be impermissible. Allowing circumvention of the statute of limitations would expand the government’s waiver of sovereign immunity, in violation of well-established law. See John R. Sand & Gravel Co., 552 U.S. at 753; 128 S.Ct. at 753 (citing United States v. Dalm, 494 U.S. 596 (1990)); Brice, 240 F.3d at 1370 (“courts should be careful not to interpret [a waiver] in a manner that would extend the waiver beyond that which Congress intended.”); Markovich, 477 F.3d at 1360 (citing and quoting Brice). The limits upon federal jurisdiction “must be neither disregarded nor evaded.” RHI Holdings, Inc. v. United States, 142 F.3d 1459, 1461 (Fed. Cir. 1998) (citing and quoting Owen Equip. & Erection Co., v. Kroger, 437 U.S. 365 (1978)).

Based on the authorities set forth above, the claim of significant aggravation in this case, raised solely as an alternative ground for entitlement without evidentiary support, could be summarily dismissed on jurisdictional grounds. Notwithstanding, the claim of significant aggravation is not dismissed at this time because it could have been presented differently, and a different presentation would have avoided the problems raised by pleading inconsistent facts. Petitioners could have maintained that they observed Chad’s developmental delays but did not associate them with autism and still do not believe that they represented the early symptoms of Chad’s autistic disorder. If the special master found, to the contrary, that Chad’s symptoms were recognizable by the medical community as early signs of an autistic disorder, Petitioners could have claimed entitlement to relief under the significant aggravation cause of action.

²⁰ This is not to say that Petitioners engaged in conduct that would be sanctionable under FRCP Rule 11, but simply to refute the proposition that there is no limit on a party’s ability to allege alternative theories based upon inconsistent facts.

²¹ See, e.g., Daniels v. United States, 532 U.S. 374, 121 S. Ct. 1578, 1580 (2001) (“A contrary rule would effectively permit challenges far too stale to be brought in their own right, and sanction an end run around statutes of limitation and other procedural barriers”)

Presentation along those lines would have resulted in no factual or legal inconsistency. The claim that Chad's autism was originally caused by his vaccines would have been dismissed as untimely filed but the significant aggravation claim would have been preserved. We are reluctant to dismiss a claim under the Vaccine Program in these circumstances, without offering Petitioner a full and fair opportunity to submit evidence and argument in support of the significant aggravation claim. Allowing the significant aggravation claim to proceed at this time does not impermissibly expand the government's limited waiver of sovereign immunity under the Vaccine Act because the claim could have been presented properly, as described above.

Respondent has repeatedly argued that the significant aggravation claim should be dismissed because Petitioners have offered no evidence to substantiate that claim. The special master will defer consideration of Respondent's motion in order to afford Petitioners additional time in which to submit evidence supporting their claim to entitlement under the significant aggravation provision of the Act. Absent proof of such entitlement, the significant aggravation claim also will be dismissed.

IV. CONCLUSION

In an Order dated July 8, 2009, the special master offered the parties the opportunity to submit additional expert evidence on the issues surrounding application of the statute of limitations. Accordingly,

- (1) For the reasons stated herein, the undersigned finds that Petitioners have not submitted preponderant evidence to establish the timeliness of their claim that Chad's autism was originally caused by vaccines. Under the rules governing allocation of the burden of proof on timeliness, Petitioners have failed to carry their burdens of production and persuasion. Therefore, Petitioners' claim that Chad's vaccinations caused the onset of his autism is dismissed as untimely; and
- (2) Petitioners' claim that Chad's vaccinations significantly aggravated his autism is not dismissed and shall be subject to further proceedings.

IT IS SO ORDERED.

s/ Dee Lord
Dee Lord
Special Master