In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

No. 05-1002V

Filed: May 15, 2008

To Be Published

MELISSA CLOER, M.D.,	*	
Petitioner,	*	Statute of Limitations, Markovich, Symptom versus Manifestation.
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Mari C. Bush, Denver, CO, for petitioner.

Lynn E. Ricciardella, United States Department of Justice, Washington, DC, for respondent.

DECISION[1]

GOLKIEWICZ, Chief Special Master.

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

On September 16, 2005, petitioner, Melissa Cloer, M.D. (Dr. Cloer), filed a Petition pursuant to the National Vaccine Injury Compensation Program[2] ("the Act" or "the Program") alleging that she "had sustained and/or significantly aggravated Multiple Sclerosis[3] (MS) as a result of receiving Hep-B immunizations in 1996 and 1997."[4] Petition (Pet.) at 1. On December 1, 2005, respondent filed a Motion to Dismiss alleging the Petition was filed outside the statutorily prescribed limitations period. Respondent's Motion to Dismiss (hereinafter R Motion to Dismiss) at 1. Multiple pleadings and affidavits were subsequently submitted by the parties addressing the issue of whether the above-captioned case was timely filed. Ultimately, a telephonic Hearing was convened to elicit testimony from petitioner's treating physician, Dr. Michael Andrew Meyer. Petitioner and respondent subsequently filed post-Hearing briefs. The issue is ripe for resolution.

Issue

The sole issue presented at this stage in the proceedings is whether Dr. Cloer's Petition for compensation for her multiple sclerosis injury was filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." §16(a)(2).[5] For the reasons set forth below the undersigned must dismiss this petition as untimely filed.

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[2] 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.A. §§ 300aa-10 et seq. (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act"). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

[3] Multiple Sclerosis (MS) is defined as: a disease in which there are foci of demyelination of various sizes throughout the white matter of the central nervous system, sometimes extending into the gray matter. Typically, the symptoms of lesions of the white matter are weakness, incoordination, paresthesias, speech disturbances, and visual complaints. The course of the disease is usually prolonged, so that the term *multiple* also refers to remissions and relapses that occur over a period of many years. Four types are recognized, based on the course of the disease: *relapsing remitting*, *secondary progressive*, *primary progressive*, and *progressive relapsing*. The etiology is unknown. Dorland's Illustrated Medical Dictionary 1669 (30th ed 2003).

[4] The undersigned notes that while petitioner alleged in her petition she "had sustained and/or significantly aggravated Multiple Sclerosis (MS) as a result of receiving Hep-B immunizations in 1996 and 1997," petitioner did not produce any evidence distinguishing between "sustained" and "aggravated" for purposes of determining whether the Petition was filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." §16(a)(2).

[5] The undersigned requested the parties to address the applicability of the Act's distinct time period for filing a claim based upon a revision to the Vaccine Injury Table. See §16(b). Respondent raised the issue in Respondent's Reply to Petitioner's Opposition to the Motion to Dismiss at 6-7. Petitioner argued that §16(b) was inapplicable. Petitioner's Response to Respondent's Argument Regarding the Applicability of §16(b). Thereafter, respondent's counsel indicated to the undersigned in a joint status conference with petitioner's counsel on May 15, 2006 that respondent agreed with petitioner's position. Given the resolution of this case, it is unnecessary to discuss the §16(b) issue.

Facts

The facts presented in this matter are uncontested, although the significance of the facts is the centerpiece of the dispute. Dr. Cloer was born on January 22, 1968. Pet. at 1. Prior to Dr. Cloer's MS injury she had no significant medical issues and enjoyed good health. Id. at 2. Dr. Cloer received a series of three Hep-B vaccinations on September 3, 1996, November 11, 1996, and April 3, 1997. Id. The following excerpt from respondent's post-Hearing brief fairly and accurately summarizes petitioner's pertinent medical records following her three Hep-B vaccinations.

1. April 28, 1998 records of UM-Columbia reveal that one year earlier petitioner complained of an "electric-like shock sensation going down [the] center of [her] back into both feet," and, in September and October 1997, petitioner lost sensation in her left arm and left hand. Petitioner's Exhibit ("Pet. Exh.") 12 at 12;

2. May 12, 1998 magnetic resonance imaging (MRI) scan; possible diagnoses included "multiple sclerosis, lyme[] disease, ADEM [acute disseminating encephalomyelitis], or other demyelinating processes." Pet. Exh. 12 at 16;

3. May 15, 1998 record of UM-Columbia noted "[p]robable early inactive non-progressive CNS [central nervous system] demyelination/MS . . . ." Pet. Exh. 12 at 17;

4. June 23, 1998 electromyography (EMG) to evaluate "numbness and tingling in the L ulnar nerve distribution." Pet. Exh. 12 at 22;

5. May 6, 1999 neurological examination by Ted Colapinto, M.D. Pet. Ex. 12 at 36. Dr. Colapinto noted petitioner's history "beg[an] approximately two years ago when she had the onset of neurological symptoms in her left hand. She complain[ed] that her left hand felt numb ... this lasted approximately two months, but gradually resolved mostly." Id. Dr. Colapinto recorded petitioner's complaints of numbness in her face, arms, and legs, and noted that she had difficulty walking. Id. He felt that petitioner's neurological symptoms "likely represent demyelinating disease." Id.;

6. June 3, 1999 follow-up visit to Dr. Colapinto noted "a lot of improvement in the symptoms in the lower extremities, but still

notice[d] some feelings of proximal weakness in the right leg, as well as some numbness of the anterior aspect of the right thigh." Pet. Exh. 12 at 41. Dr. Colapinto expressed continuing concern that petitioner had a demyelinating disease. Id.;

7. November 26, 2003 record of Dr. Wood detailing petitioner's medical history:

> [Melissa] actually believes that she has had problems dating from 1997 when she was in Missouri. She had episodes of variable weakness and numbness of her legs, at one time numbness of her right face. She had an MRI of the brain in 1997 which reportedly was suspicious for demyelinating areas and also had spinal cord MRIs reportedly unremarkable . . . She had actually been recommended for treatment for MS, but did not take any. Pet. Exh. 13 at 17.[6]

Respondent's Reply to Petitioner's Post-Hearing Brief (hereinafter R. Post-Hearing Reply) at 3-4.

Dr. Cloer was given a "provisional" diagnosis of MS on November 26, 2003 by her treating neurologist Dr. Wood subsequent to his obtaining Dr. Cloer's medical history and results of an MRI examination. Pet. Exh. 13 at 16-19.

Dr. Cloer applied for and was awarded Social Security Disability in 2004. Pet. Exh. 14 at 1-2. As part of that process Dr. Cloer was evaluated by Dr. James P. Metcalf on June 17, 2004. Id. at 3. Dr. Metcalf noted Dr. Cloer reported she "first begin [sic] to have some symptoms consistent with MS in 1997," however, her "symptoms waxed and waned until the fall of 2003 when she begin [sic] to have manifestations of the full blown disease." Id.

Dr. Cloer reported to the Vaccine Adverse Event Reporting System (VAERS) on October 11, 2004, that she experienced numbness and tingling after her first two Hep-B vaccinations.

[6] The undersigned notes that Dr. Johnson, who evaluated Dr. Cloer in August of 2002 for symptoms consistent with retrobulbar neuritis, submitted an affidavit in this case stating "[t]o the extent Dr. Wood's note indicates that Dr. Cloer was recommended for treatment for MS, but did not take any, that would not apply to my care and treatment of Dr. Cloer." Pet. Exh. 21 at 2. Dr. Johnson also disputes a notation in Dr. Wood's November 26, 2003 record indicating Dr. Cloer was urged to get treatment for retrobulbar neuritis in the fall of 2002. Dr. Johnson states Dr. Cloer had "symptoms in the left eye when I consulted with her. I did not urge any treatment." Id. The undersigned finds it is not necessary to determine whether or not Dr. Johnson recommended Dr. Cloer receive MS treatment in 2002 to resolve the issue presented in the instant case.

Pet. Exh. 19 at 2. Dr. Cloer stated these symptoms were followed by "Lhermitte's"[7] approximately one month after her third vaccination. Id.

Affidavits of Melissa L. Cloer, MD

Dr. Cloer, petitioner, submitted a sworn affidavit as part of the Petition in this case. The critical portion relevant to the issue at hand states as follows:

> 12. In late 2003, I was diagnosed with multiple sclerosis. While I had experienced some isolated symptoms prior to that time, it wasn't until November 2003 that probable multiple sclerosis was diagnosed.
>
> 13. For instance, in 1997 I had an electric shock sensation in my spine and numbness in my left forearms and hand. My family physician, Dr. Susan Pereira, prescribed Motrin and the symptoms resolved over a short period of time. An MRI done on May 12, 1998 included differential diagnoses of MS, Lymes Disease, ADEM or other demyelinating processes. Dr. Meyer, the neurologist, described my problem as a "probable early inactive non-progressive" condition.

Pet. Exh. 2 at 3. As the legal issue of whether her Petition was filed timely developed, petitioner thereafter filed a second affidavit. Pet. Exh. 26. The affidavit provides in relevant part as follows:

> 4. I have been asked to address when any of the signs, the first occurrence of the first symptom or manifestation of onset of my Multiple Sclerosis (MS) lasted six months or more.
>
> 5. It was not until late 2003 or early 2004 that any signs, the first symptoms or manifestation of onset of my Multiple Sclerosis persisted for six months or more.

Id.

Affidavits from Dr. Michael Meyer

Dr. Meyer is a neurologist who treated petitioner in 1998, about one year following her immunizations. Dr. Meyer's first affidavit was filed on February 16, 2007. Pet. Exh. 20. In relevant part, Dr. Meyer stated that at the time he examined Dr. Cloer, "she had the manifestations of onset of what can be termed 'singular sclerosis'. . . [and] she had what appeared to be early inactive non-progressive CNS demyelinating disease." Id. He also stated that:

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[7] Lhermitte's phenomenon is discussed at n.8, infra at p.7.

10. At the time I evaluated Dr. Cloer in 1998, she had not yet been formally diagnosed with the clinical syndrome complex of multiple sclerosis (MS).

11. There had been no manifestation for the onset of clinically definite multiple sclerosis during the time period I evaluated Dr. Cloer.

Id. Following a number of status conferences between the undersigned and counsel discussing the statute of limitations issue, petitioner filed a second affidavit from Dr. Meyer. Pet. Exh. 23. In that affidavit, Dr. Meyer expanded on and explained statements he made in his earlier affidavit. Id. Relevant to the issue at hand, Dr. Meyer maintained that when he evaluated Dr. Cloer in 1998, she did not meet "formal diagnostic criteria for clinically definite MS." Id. He explained that at that time in 1998, Dr. Cloer's "singular demyelinating change could have remained a clinically isolated event with no sequela." Id.

Following the Court of Appeals for the Federal Circuit's decision in Markovich v. Secretary of HHS, 477 F.3d 1353 (Fed. Cir. 2007), which addressed the appropriate legal interpretation of the Act's statute of limitations, Dr. Meyer issued a third affidavit. Pet. Exh. 25. In this affidavit, Dr. Meyer repeats the medical points made in his two prior affidavits. In addition, having been provided by counsel a copy of the Markovich opinion, Dr. Meyer attempts to interpret and apply Markovich to the medical facts of Dr. Cloer's case. Obviously, it is not Dr. Meyer's role as a medical expert to interpret the law, and his efforts were not helpful.

After reviewing Dr. Meyer's three affidavits and discussing them with counsel, it was clear that Dr. Meyer's testimony was necessary to understand several points, including what he meant by "she had the manifestations of onset of what can be termed 'singular sclerosis'" in 1998, Pet. Exh. 20, and "[t]here had been no manifestation for the onset of clinically definite multiple sclerosis during the time period I evaluated Dr. Cloer." Id. A Hearing was conducted to take Dr. Meyer's testimony.

Dr. Meyer's Testimony

Michael Andrew Meyer, M.D., testified without objection as an expert in the field of neurology with a speciality in MS. Hearing Transcript (hereinafter "Tr. at _") at 9. Dr. Meyer testified consistently with his affidavits. He was extremely knowledgeable about the medical issues involved and, having reviewed the medical records, was well-prepared to discuss the case. The undersigned found Dr. Meyer to be a very credible witness. However, at times Dr. Meyer's testimony appeared contradictory and confusing. But this was not the fault of Dr. Meyer, and was not interpreted in any way to detract from his credibility. The confusing testimony was the direct result of questions from petitioner's counsel designed to finesse the facts of this case into the legal standard crafted by the Federal Circuit in Markovich. Dr. Meyer struggled at times with his answers to these questions, answers the undersigned found unhelpful. Dr. Meyer's testimony regarding the medical issues was clear and convincing. These issues will be discussed later.

During his testimony, Dr. Meyer summarized petitioner's medical history beginning when he first evaluated petitioner on April 28, 1998 at the University of Missouri Medical Clinic. Tr. at 11; Pet. Exh. 12 at 12. Dr. Meyer testified that his notes from his initial evaluation with Dr. Cloer indicate she complained of experiencing one year ago, in 1997, "electric like sensations going down the center of her back to both feet with forward head flexion"[8] for several months. Tr. at 12; Pet. Exh. 12 at 12. Dr. Cloer also reported to Dr. Meyer that she experienced "decreased sensation at the left posterior shoulder area and back" in 1997. Id. Dr. Meyer explained based upon the history taken, as well as his physical examination of Dr. Cloer, he ordered an MRI scan "to rule out MS." Id. at 12-13. Dr. Meyer testified that in 1998 "he did not think she [Dr. Cloer] had definite MS at that time." Tr. at 15, 34. However, Dr. Meyer testified that in retrospect petitioner's experience of Lhermitte's sign in 1997 was the **first symptom** of Dr. Cloer's MS. Id. at 49-50, 52, 54-55.

Legal Standard

Pursuant to the Vaccine Act petitioners may be compensated for injuries caused by certain vaccines. 42 U.S.C. §§ 300aa-10 to -34. However, the Vaccine Act provides statutory deadlines for filing program petitions at § 300aa-16. In relevant part, the Vaccine Act provides:

> 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 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 . . . .

§ 300aa-16(a)(2) (emphasis added). The Vaccine Act is a waiver of the United States' sovereign immunity and accordingly "must be strictly and narrowly construed." Markovich v. Secretary of HHS, 477 F.3d 1353, 1356 (Fed. Cir. 2007). The Federal Circuit has instructed "courts should be careful not to interpret a waiver in a manner that would extend the waiver in a manner beyond that which Congress intend." Markovich, 477 F.3d at 1360, citing Brice v. Secretary of HHS, 240 F.3d 1367, 1370 (Fed. Cir. 2001). The Circuit's decision in Markovich directly addressed the question of "what standard should be applied in determining the date of 'the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury,'" Markovich, 477 F.3d at 1356, by holding "'the first symptom or manifestation of onset,' for purposes of §300aa-16(a)(2), is the first event objectively recognizable as a sign of a vaccine

[8] Dr. Meyer testified at the Hearing that this "sensation" experienced by Dr. Cloer is Lhermitte's phenomenon. Tr. at 34-35. Lhermitte's sign is defined as "the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other disorders of the cervical cord." Dorland's Illustrated Medical Dictionary 1700 (30th ed 2003).

injury by the medical profession at large." Id. at 1360.[9] Accordingly, petitioners have 36 months from the first recognizable sign of their alleged vaccine injury to file their claim.

The Circuit explained in Markovich that "the terms of the Vaccine Act demonstrate that Congress intended the limitation 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." Id. at 1358. The Circuit elaborated that by choosing to "start the running of the statute of limitations period on the date the first symptom or manifestation of the onset occurs, Congress chose to start the running of the statute before many petitioners would be able to recognize with reasonable certainty, the nature of the injury." Id. The Court noted that the Act has "consistently been interpreted" to include "subtle" symptoms or manifestations of onset as triggers of the Act's statute of limitations. Id. The Court stressed that the words "symptom" and "manifestation of onset" are in the disjunctive as used in the Act and that the words have different meanings. Id. at 1357. Thus, **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," whereas a **manifestation of onset** "is more self-evident of an injury and may include significant symptoms that clearly evidence an injury." Id. Accordingly, the Court found that the Act's statutory standard of first symptom or manifestation of onset could include subtle symptoms that a petitioner would recognize "only with the benefit of hindsight, after a doctor makes a definitive diagnosis of the injury" and would be "recognizable to the medical profession at large but not necessarily to the parent." Id. at 1358, 1360 (citing Goetz v. Secretary of HHS, 45 Fed. Cl. 340, 342 (1999)). Thus, the Circuit in interpreting the Act's statute of limitations, rejected applying a "subjective standard that focuses on the parent's view" of the timing of onset in favor of an "objective standard that focuses on the recognized standards of the medical profession at large." Id. at 1360.

Discussion

The undersigned notes that the complexity of the issues presented in this case evolved with the development of the case law. The initial arguments and discussions took place within the context of the Setnes ruling, which unquestionably presented much reasonable room for

[9] Although not directly stated, the Markovich decision appears to have found that Setnes v. Secretary of HHS, 57 Fed. Cl. 175 (2003) was incorrectly decided. In Setnes, the Court of Federal Claims determined that "[w]here there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the 'occurrence of the first symptom.'" Setnes, 57 Fed. Cl. at 179. The Setnes court stated that because the symptoms of autism develop "insidiously over time" and the child's behavior cannot readily be connected to an injury or disorder, the court's inquiry into the onset of the autistic condition is not limited to a determination of when the first symptom or manifestation of the condition occurred, but rather is informed by the child's subsequent medical or psychological evaluations of when the "manifestation of onset" occurred. Id. at 181. The Federal Circuit found a "significant problem with the rationale of Setnes" in that Setnes "effectively" required evidence of a "symptom *and* manifestation" whereas the Act requires either a symptom or manifestation of onset, whichever occurs first, to trigger the statute of limitations. Markovich, 477 F.3d at 1358.

disagreement and debate. However, with the issuance of the Circuit's decision in Markovich, the standard for resolving issues under the Act's statute of limitations has crystalized and the room for debate narrowed greatly. In light of Markovich, the issues presented in this case are now relatively straightforward.

After considering the entire record and the parties' respective arguments, this case must be dismissed as untimely. It is clear from the medical records, petitioner's affidavits, as well as Dr. Meyer's affidavits and testimony that the first symptom of the onset of Dr. Cloer's MS was in 1997. Since the Petition was filed eight years later, the Petition was untimely. See §16(a)(2).

Dr. Meyer conceded several times at the August 30, 2003 hearing that in **retrospect** the first symptom of Dr. Cloer's MS was the Lhermitte's sign which Dr. Cloer experienced in 1997.

THE COURT: [Y]ou said back in 1998 [petitioner] had a singular sclerosis. Looking back at this case now from today's vantage point is that singular sclerosis part of what was ultimately diagnosed as multiple sclerosis?

DR. MEYER: Retrospectively I think that there was a relation, and I think that it's probably linked in some way. You know, we're talking about a disease that's not uncommon, and prospectively the symptoms could have represented many different things. The [Lhermitte's] phenomenon that she does talk about or had talked about does raise some concern about MS specific type symptoms.

Tr. at 49.

THE COURT: [F]rom today with the totality of this record was that singular sclerosis part what was ultimately diagnosed as multiple sclerosis?

DR. MEYER: I can't say definitely. I say that there's a likelihood that there's a relationship, that there's probably a link. A more yes than no, but I can't say definitely.

THE COURT: Okay. So I interpret that to mean on a probability scale that you would say it was more probably than not related?

DR. MEYER: Yes. More probably yes than no.

Tr. at 49-50.

THE COURT: [L]ooking back at this retrospectively with this record you have in front of you, on a probability scale what's the first evidence of her multiple sclerosis?

WITNESS: I think that the first MS related symptom was the [Lhermitte's] phenomenon that she had in 1997 where she would have the electric shock like sensation going down her back when she would bring her head forward.

Tr. at 52.

In response to questioning, Dr. Meyer agreed that petitioner had a demyelinating disease in 1998. Tr. at 37. However, she did not have the requisite number of lesions to have clinically definite multiple sclerosis. Id. Eventually, petitioner's symptoms progressed to where it became multiple sclerosis. Tr. at 41. Dr. Meyer stated that although it is difficult and individual cases vary, a retrospective linking of past symptoms to a current diagnosis of multiple sclerosis can "find the connection often." Tr. at 39.

Dr. Meyer's retrospective testimony is consistent with the medical records in noting a demyelinating disease in Dr. Cloer in 1998. The contemporaneous medical records are replete with references to demyelinating symptoms and to possible MS. See Pet. Exh. 12 at 17 (Dr. Meyer's 5/15/98 progress notes states "[p]robable early inactive non-progressive cns [central nervous system] demyelination/ms . . ."); Id. at 16 (5/12/98 MRI notes a clinical history of "DYMILANATING [sic] MS" (emphasis in original) and states under "IMPRESSION" "Multiple Sclerosis, Lymes Disease, ADEM, or other Demyelinating Processes"); Id. at 37 (Noting a two-year history of onset of neurological symptoms, Dr. Colapinto's posits in a May 6, 1999 letter that "[Dr. Cloer] is having waxing and waning neurological symptoms in multiple areas of her body. I fear that this may likely represent demyelinating disease."). Also, later records date the onset of Dr. Cloer's MS to the events of 1997. See Pet. Exh. 13 at 17 (Dr. Wood's 11/26/03 history noting that Dr. Cloer "had an MRI of the brain in 1997 which reportedly was suspicious for demyelinating areas . . ."); Pet. Exh. 14 at 3 (Dr. Metcalf's 6/17/04 examination of Dr. Cloer wherein he notes that Dr. Cloer "**states** she first began to have some symptoms consistent with MS in 1997.") (emphasis added); Pet Exh. 13 at 35 (Dr. Wood, providing medical information for a student financial aid application for Dr. Cloer in February of 2005, states "MRI proven Multiple Sclerosis of brain and spinal cord, 8 yrs duration," i.e., MS began in 1997).

In addition, petitioner's first affidavit acknowledged that in 1997, she experienced an "electric shock sensation" in her spine. Pet. Exh. 2 at 2. Petitioner also filed a VAERS report in 2004 stating that she suffered Lhermitte's approximately a month following her immunization. Pet. Exh. 19 at 2. Dr. Meyer testified that the shock-like sensation experienced by petitioner was Lhermitte's phenomenon, tr. at 34-35, and that the "first MS related symptom was the [Lhermitte's] phenomenon that she had in 1997." Id. at 52.

Dr. Cloer's onset of MS also can be traced through the testimony of Dr. Meyer. Dr. Meyer first evaluated Dr. Cloer in 1998 and stated that Dr. Cloer had "demyelinating disease" at that time, but that "she did not yet have the requisite lesions in multiple areas of her central nervous system to qualify as clinically definite multiple sclerosis." Tr. at 37. Dr. Meyer explained that there is often a significant delay between the initial symptoms of MS and a definitive diagnosis of MS. Based upon the study of patient histories it is known that "patients who wind up with a definitive diagnosis of MS when they are looked [at] retrospectively there can be a great delay . . . a gap of many years." Tr. at 38. Dr. Meyer stated that the initial symptoms may progress, may wax and wan, or may never return. Tr. at 40, 43. It is a "fickle" disease. Tr. at 43. However, regarding Dr. Cloer, he stated:

> From what I know about what happened, what transpired over the years, that things did change, and in 2002 and 2003 she had progressed, changed.

Tr. at 40-41. In Dr. Cloer's case, Dr. Meyer testified her condition "became multiple sclerosis." Tr. at 41. Thus, Dr. Meyer agreed, it can be apparent retrospectively that symptoms which are part of the "same demyelinating process" may "culminate in a diagnosis of multiple sclerosis many years later." Tr. at 39. Dr. Meyer elaborated "retrospectively you can look back in this pool of patients and find the connection often," tr. at 39, and in Dr. Cloer's case the **"first sign to a clinician retrospectively was the [Lhermitte's] phenomenon back in 1997."** Tr. at 55 (emphasis added); see id. at 49, 50, and 52.

The Act provides a window of three years from "the first symptom or manifestation of onset" to file a vaccine-related claim. §16(a)(2). The Federal Circuit provided recently in Markovich the precedential interpretation of that section of the Act. Dr. Meyer testified that the first symptom of Dr. Cloer's MS occurred in 1997. The contemporaneous medical records support Dr. Meyer's testimony. Petitioner's contemporaneous histories given to treating doctors support the finding of the first symptom of her MS occurring in 1997. Lastly, petitioner's affidavit and statements on her VAERS reports state that the first symptom occurred in 1997. Accordingly, the undesigned finds that the overwhelming evidence supports a finding that the first symptom of Dr. Cloer's MS occurred in 1997. Thus, petitioner had three years, or until the year 2000, to file her vaccine injury claim. §16(a)(2). Petitioner filed her claim on September 16, 2005. Clearly, petitioner filed her Petition beyond the Act's three-year statute of limitations. Accordingly, respondent's Motion to Dismiss is hereby granted.

Petitioner argues that the Vaccine Act's statute of limitations should not begin to run in the instant case until November of 2003 or thereafter based primarily upon the following: petitioner was not diagnosed with MS until 2003, neither petitioner nor her medical care providers were aware of a potential link between vaccinations and MS until after 2003, and MS poses diagnostic challenges. Thus, petitioner argues:

> The medical community at large would not have authoritatively associated her condition, injury or problems to MS until 2003. It

> wasn't until after the November 2003 diagnosis of MS, based on accepted criteria, that Dr. Cloer became aware of the potential link to her earlier immunizations. There is no indication that other members of the "medical community at large" would have so linked her problems to the vaccinations until 2003 or thereafter.

Petitioner's Post-Hearing Brief at 9.

Even assuming each of these arguments to be factually correct, these arguments fail, because petitioner misunderstands or chooses to ignore the standard enunciated by the Federal Circuit in Markovich and the plain language of the statute.

Throughout petitioner's briefs and even in questions posed to Dr. Meyer, petitioner raises the argument that there was no diagnosis of multiple sclerosis until November 2003. See Petitioner's Amended Brief in Opposition to Respondent's Motion to Dismiss (hereinafter P. Amended Brief in Opposition) filed February 17, 2006 at 3; see also Tr. at 26-27. Petitioner argues the statute of limitations should begin to run in 2003 at the earliest, relying upon Dr. Meyer's testimony that prior to petitioner's 2003 MRI, the medical community at-large would not have diagnosed Dr. Cloer with MS. Tr. at 27, 47, 55. Closely related to the argument of when the diagnosis was made is petitioner's contention that the "manifestation of onset" of Dr. Cloer's MS was in 2003. Petitioner's Post-Hearing Brief at 6; Tr. at 27-28. As discussed, see supra at pp. 7-8, the commencement of the Vaccine Act begins upon the *first symptom or manifestation* of the alleged vaccine related injury. The Federal Circuit interpreted that statutory language in the disjunctive, and recognized the "dissimilar meaning of the words "symptom" and "manifestation of onset." Markovich, 477 F.3d at 1357. Dr. Meyer testified, and the medical records support, that the first symptom of petitioner's MS occurred in 1997. Having found the first symptom of Dr. Cloer's MS occurred in 1997, for purposes of the disjunctive standard of §16(a)(2), it is thus irrelevant when the manifestation of onset occurred. Likewise, also irrelevant are petitioner's continued arguments regarding when the diagnosis of MS occurred. The Federal Circuit was very clear that diagnosis is not the test for purposes of the statute of limitations. See id. ("For example, in this case, the eye-blinking episode was a symptom of a seizure disorder without any diagnosis. . . ."); see also id. at 1358 ("[A] petitioner typically will recognize that a particular symptom constitutes the first symptom or manifestation of the onset of a certain injury only with the benefit of hindsight, **after** a doctor makes a definitive diagnosis of the injury.") (emphasis added).

A second argument that permeates petitioner's briefs and questions is that petitioner was not diagnosed with a **vaccine injury** before 2004. Petitioner's Post-Hearing Brief at 6; Tr. at 14, 20, 23, 26, and 28. Petitioner misreads Markovich. The Court's holding was that for purposes of §300aa-16(a)(2), "the first symptom or manifestation of onset" is the "first event objectively recognizable as a sign of a vaccine injury by the medical profession at large." Markovich 477 F.3d at 1360. There is no requirement that the **vaccine injury** be diagnosed. In this case, the first "sign" of petitioner's MS, the alleged vaccine injury in this case, recognized by Dr. Meyer, a

representative of the medical profession, tr. at 8, was the Lhermitte's phenomenon that occurred in 1997. Tr. at 52. Dr. Meyer's position is corroborated by both the medical records and petitioner's affidavit. Accordingly, the first symptom for triggering the statute of limitations was the Lhermitte's phenomenon Dr. Cloer experienced in 1997.

Petitioner further argues the statute of limitations period should begin to run in 2003, because prior to this time petitioner did not suffer "the residual effects or complications of such illness, disability, injury or condition for more than six months," as required by §11(c)(1)(D)(I) and thus could not have filed a valid petition. The undersigned agrees with respondent,

> whether or not a petitioner has shown that an injury has persisted for more than six months has no bearing on whether the petition was filed within 36 months of the first symptom or manifestation of onset of that injury. Section 11(c)(1)(D)(I) does not extend the filing date of a petition until a time when a petitioner's alleged vaccine-related injury persists for at least six months.

R. Post-Hearing Reply at 5.[10]

Petitioner argues lastly that the statute of limitations should be tolled in the instant case as "there was no reason to suspect that Dr. Cloer's symptoms were in fact symptoms of MS" and as distinguishable from the Brice case as "there was neither a subjective nor an objective basis for drawing such a connection until some three years before the filing of Dr. Cloer's petition." P. Amended Brief in Opposition at 15. The undersigned disagrees. Upon taking petitioner's medical history and reviewing her MRI in 1998, Dr. Meyer did suspect MS as a potential diagnosis of petitioner's injury. In fact petitioner's medical records are replete with indications that her injury was potentially connected to MS in 1997 and 1998. See supra at pp. 2-4, and 10. Further, the Federal Circuit has found that "the statute of limitations [in the Vaccine Act] begins to run upon the first symptom or manifestation of onset of injury, even if the petitioner reasonably would not have known at that time that the vaccine caused an injury." Brice v. Secretary of HHS, 240 F.3d 1367, 1373 (Fed. Cir. 2001). In Markovich, the Circuit reaffirmed its' holding in Brice that "equitable tolling is not available for claims arising under §300-16(a)(2)." Markovich, 477 F.3d at 1358.

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[10] The undersigned notes petitioner raised a number of constitutional arguments in her filings in opposition to Respondent' Motion to Dismiss. Specifically, petitioner argues that the Vaccine Act's Statute of Limitations violates the Due Process or the Equal Protection Clause of the US Constitution's Fifth Amendment. P. Amended Brief in Opposition at 17-23. Respondent strongly opposed petitioner's constitutional arguments. Respondent's Reply to Petitioner's Opposition to Respondent's Motion to Dismiss at 9-14. Petitioner's arguments were not well-developed. In any event, the undersigned finds it unnecessary to engage in a lengthy analysis since the criteria for eligibility has been analyzed and found to pass constitutional scrutiny. Leuz. v. Secretary of HHS, 63 Fed. Cl. 602 (2005).

For the reasons stated above and based upon the undersigned's review of the record as a whole, the undersigned finds that a preponderance of the evidence does not support that the Petition was filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury" as required by the Vaccine Act. Petitioner's claim is dismissed. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master