In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 03-1280V

Filed: January 27, 2006

KELLEY ARMSTRONG, by her mother and next friend LAURA ARMSTRONG,	*	
Petitioner,	*	
v.	*	TO BE PUBLISHED
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

***Sheila A. Bjorklund**, Lommen, Nelson, Cole & Stageberg, P.A.*, Minneapolis, MN, *for petitioner.*

***Melonie J. McCall**, United States Department of Justice,* Washington, DC, *for respondent.*

DECISION DISMISSING PETITION FOR LACK OF JURISDICTION

GOLKIEWICZ, Chief Special Master

On May 28, 2003, petitioner, then acting pro se, filed a petition [hereinafter "Pet."] for compensation on behalf of her daughter, Kelley Armstrong, under the National Vaccine Injury Compensation Program [hereinafter "the Act" or "the Program"]. Petitioner claims that Kelley suffered the injury of rheumatoid arthritis as a direct result of the hepatitis B vaccine that she received on July 16, 1999. Pet. at 1. However, prior to evaluating the substance of petitioner's petition, on February 15, 2005, respondent filed a motion to dismiss the case alleging that the petition was filed untimely. Respondent's Motion to Dismiss, filed Feb. 15, 2005 [hereinafter "Motion"]. After a full review of the record, the undersigned finds that the petition must be dismissed due to being filed beyond the applicable statute of limitations. A full discussion follows.

PROCEDURAL HISTORY

On May 28, 2003, petitioner filed a petition for compensation alleging that her daughter, Kelley Armstrong, suffered the injury of rheumatoid arthritis as a result of the hepatitis B vaccine

that she received on July 16, 1999. Pet. at 1. At the time of filing the petition, petitioner was acting pro se. On February 23, 2004, petitioner informed the court in writing that she had obtained legal representation, and that counsel was in the process of contacting experts for review of the case. Subsequently, on December 10, 2004, petitioner filed additional records for Kelley, as well as the medical opinion proffered by Dr. U. Evren Akin, MD [hereinafter "P. Ex. Rep."]. Dr. Akin opined that Kelley "likely developed seronegative enthesopathy-arthropathy subtype of juvenile spondyloarthropathy [hereinafter "SEA"] in association with an immune reaction to the Hepatitis B vaccination on July 16, 1999." P. Ex. Rep. at 1-2.

Subsequent to petitioner's filings, pursuant to a status conference, respondent filed on February 15, 2005 a motion to dismiss alleging the petition's untimely filing. Motion at 1-2. In the motion, respondent argues that the petition was "filed more than 36 months after the date of the occurrence of the first symptom or manifestation of onset of the alleged vaccine injury." Id. Respondent correctly notes that 42 U.S.C. § 300aa-16(a)(2)[1] of the Act requires that a petition be filed "within 36 months after the date of the occurrence of the *first symptom or manifestation of onset.*" Id. at 8 (emphasis in original). Respondent also notes that petitioner's expert stated in the expert report that Kelley had onset of her joint pain within days after the July 16, 1999 administration of the vaccine. Id. Thus, respondent argues that this evidence, along with other evidence in the medical records, would require the petition's filing no later than July 2002 to meet the Act's 36 month filing requirement. Id. It follows that since the petition was filed on May 28, 2003, it must be dismissed as jurisdictionally barred. Id. Respondent relies on Brice v. Secretary of Health and Human Services, 240 F.3d 1367, 1374 (Fed. Cir. 2001), *cert. denied sub nom.* Brice v. Thompson, 534 US 1040 (2001), in support of this argument. Id.

In response, petitioner filed a "Memorandum [hereinafter "P. Res."] and Appendix [hereinafter "Appx."] in Opposition to Respondent's Motion to Dismiss" on April 11, 2005. Relying on Judge Futey's decision in Setnes v. Secretary of Health and Human Services, 57 Fed. Cl. 175 (2003), petitioner asserts that her petition was timely filed because it was brought well within 36 months of the manifestation of onset of her daughter, Kelley's, alleged vaccine injury. P. Res. at 2. This is because, while according to her expert, Dr. Akin, Kelley's injury began a few days after her hepatitis B vaccination, the diagnosis of her injury was not possible until April of 2002. P. Ex. Rep. at 6-7. In addition, petitioner contends that "[t]he contemporaneous medical records in this case indicate that by the Fall of 2000 Kelley Armstrong was complaining of aches and pains in her joints." P. Res. at 13. Based upon this cumulative information, petitioner argues that the "manifestation of onset of Kelley's vaccine-related injury was sometime between August 2000 and April 2002," id. at 7, and thus, petitioner concludes that the petition, filed in May of 2003, was filed within the statute of limitations period of the Act. Id. at 14.

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[1]The statutory provisions governing the Vaccine Act are found at 42 U.S.C. §§ 300aa-10 to 300aa-34 (2003). Hereinafter, for ease of citation, all references will be to the relevant subsection of 42 U.S.C. § 300aa.

Petitioner also relies on Massard v. Secretary of Health and Human Services, 25 Cl. Ct. 421, 424 (1992), which petitioner argues defines when a cause of action accrues. P. Res. at 8. According to petitioner, "'[a]ccrual is a date on which the statute of limitations begins to run; not the date on which the wrong that injured [a] plaintiff occurs, but the date when plaintiff discovers that he has been injured.'" Id. (citing Massard, 25 Cl. Ct. at 425). More specifically, petitioner asserts that the injury that Kelley sustained had "no clear start and cannot be reduced to a single, identifiable symptom or test." P. Res. at 13. In Kelley's case, the hepatitis B vaccine triggered an injury to Kelley's joints, but because many of the symptoms were "vague and subtle," Kelley's treaters were not able to diagnose her disease until, at the earliest, April of 2002. Id. Petitioner's expert, Dr. Akin pointed out that only in retrospect can one trace the symptoms of this progressive immune response disorder back to shortly after receipt of the hepatitis B vaccine – that there is no possible way that SEA would have been suspected at that time. Id. at 6. Petitioner argues that "[p]rudence would mandate that in determining when Kelley Armstrong's cause of action under the Act accrued, the court must not hinge its decision on the 'occurrence of the first symptom,' but rather on when the onset of the SEA was evident." Id. at 13-14. Accordingly, petitioner requests that the court deny respondent's motion to dismiss. Id. at 2.

FACTUAL BACKGROUND

A. Medical History

Kelley Armstrong was born on May 22, 1988 as a full term baby with no complications during her mother's pregnancy. Petitioner's Affidavit [hereinafter "Pet. Aff."], filed Sept. 4, 2003 at 1. According to her mother, Laura Armstrong, Kelley was a "healthy, active, athletic young girl" until July 16, 1999, the date on which she received her hepatitis B vaccination. Id. On that day, Mrs. Armstrong and Kelley traveled to the Anderson County Health Department to receive a school-required hepatitis B vaccination. Id. Kelley's mother stated in her affidavit that after the vaccination, after they returned to the car and had started to drive away, Kelley "was slumped down in her seat, tongue hanging out, hands pulled up to her tight to her chest[,] jerking back and forth[,] bent at the elbows, eyes were rolling around." Id. These symptoms purportedly lasted about three minutes. Id. Mrs. Armstrong believed that Kelley was having a seizure and proceeded to return to the clinic for medical intervention. Id. At that point, Kelley apparently had another seizure with the same symptoms, this time lasting less than three minutes. Id. Kelley tried to get out of the car when they returned to the health department, at which time "she stood up and was walking from side to side [sic] as if dizzy and fell down," after which Mrs. Armstrong and a bystander carried her back to the clinic. Id. The nurses and a doctor at the clinic believed that the events were due to a fainting spell rather than the vaccine, but nonetheless, a report was filed with the Vaccine Adverse Event Reporting System [hereinafter

"VAERS"][2]. Id.; Petitioner's Medical Records, filed Aug. 3, 2003 [hereinafter "P. Med. Recs."][3] at 14.

Mrs. Armstrong described the changes in Kelley's behavior in detail in her affidavit following the vaccination. These "changes" were also recorded in contemporaneous medical records. The following is a brief synopsis of the petitioner's affidavit as well as Kelley's medical records.

In response to the events that occurred on July 16, 1999, Kelley saw her pediatrician on July 19, 1999. P. Aff. at 2; P. Med. Recs. at 5-7. The doctor did not believe that Kelley's symptoms were related to the vaccine, although the doctor recommended that Kelley not receive another hepatitis B shot. P. Aff. at 2; P. Med. Recs. at 3, 7, 15. An EEG and brain MRI were performed and came back normal. P. Med. Recs. at 10, 11. On August 18, 1999, Mrs. Armstrong took Kelley to see a family practitioner after Kelley continued to complain of "headache, fatigue, joint pain, and tingling." P. Aff. at 2; P. Med. Recs. at 19. Mrs. Armstrong reports that the doctor was apologetic, but had never heard of such a reaction to the vaccine. P. Aff. at 2.

According to petitioner's affidavit, Kelley continued to remain active after the July 16 vaccination, for example, by attending band practice three times a week and seeing friends at the local gym where she tumbled. Id. She complained of her hand and wrist area hurting and sometimes giving out on her, as well as her knees, when she tumbled. Id. Mrs. Armstrong attributed the symptoms to growing pains, noting that Kelley "went from a size 6-½ shoe size to 9-½ [shoe size] in a couple of months." Id.

The next medical records describe doctor visits to Dr. Martin in March and May of 2000 complaining of chest congestion, cough, and fever. Id.; P. Med. Recs. at 18, 20. She was diagnosed with pneumonia on May 10, 2000. P. Aff. at 2; P. Med. Recs. at 20. At that point, the family moved to California, where Kelley began swimming and joined the local swim team. P. Aff. at 2. Her mother reports that "[s]he loved to swim and felt her best in the water [where] 'nothing hurt her.'" Id. She tried tumbling again, but her "joints hurt too much." Id. In her affidavit, recalling that period of time and the months following, Mrs Armstrong noted that

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[2]The VAERS reporting system is a national program that monitors the safety of vaccines after they are licensed. The VAERS system is managed by the US Food and Drug Administration and the US Centers for Disease Control. Any person can report a suspected vaccine reaction to VAERS.

More information regarding the VAERS reporting system can be found at http://www.vaers.hhs.gov/pdf/VAERS_brochure.pdf.

[3]Petitioner did not paginate the submitted medical records. For convenience, the undersigned numbered the records starting with Kelley's vaccination record from "The Children's Clinic" as page 1.

Kelley developed chronic allergy problems in addition to her joint pains. Id. There is only one medical record between August 2000 and October of 2001. That record reflects that Kelley saw a doctor in California for swollen glands on August 14, 2000. Id.; P. Med. Recs. at 21.

The family moved back to North Carolina in 2001, where there was no local pool for Kelley to obtain relief from her painful joints. P. Aff. at 2. Mrs. Armstrong added that over the summer of 2001, Kelley's symptoms began to worsen and she seemed to have chronic sinus congestion, headaches, weakness and fatigue, along with joint and chest pain. Id. at 2-3. Mrs. Armstrong noted that "[s]he wasn't as sharp and quick to respond with answers" and was not reading like she had in the past. Id. at 3. At the suggestion of their doctor, the Armstrong's added a whole house filter system, had the soil tested and their carpets cleaned, and installed a water filtration system, none of which seemed to help Kelley. Id.

As noted above, there were no other additional medical records reflecting any illness between August 14 of 2000 and October of 2001, although Mrs. Armstrong states that during that period "Kelley developed chronic allergy problems in addition to her joint pains." Id. at 2. The next medical record provided has a date of October 23, 2001. P. Med. Recs. at 25. At that time, Mrs. Armstrong received notice from Kelley's school that someone had developed meningitis, and thus took Kelley to the doctor presumably as a precaution. P. Aff. at 3. At the October 23, 2001 visit, Kelley reported symptoms of cough, headache, sore throat, and fever having occurred for ten days. Id. at 3; P. Med. Recs. at 23, 25. Several subsequent visits were made in the following months. P. Med. Recs. at 26, 27. In December of 2001, Kelley was exposed to a friend with "walking pneumonia" and saw the doctor to be tested for the disease. P. Aff. at 3; P. Med. Recs. at 28. Mrs. Armstrong noted that at this time Kelley "was sleeping and tired all the time as well as dizzy." P. Aff. at 3.

Kelley was subsequently referred to an allergist, Dr. Andrea Lantz, MD, whom she visited in January of 2002. P. Med. Recs. at 31. The chief complaints that were recorded were headaches, cough, and dizziness. Id. at 33. During a history of illness provided by the parents it was recorded that "Kelley had been a normal[,] healthy child until eighteen months ago when she received the hepatitis B vaccine. She experienced an apparent seizure and has had declining health [] since that time." Id. at 34. After some tests, Kelley was diagnosed with allergies to two tree pollens, one weed pollen, and a mold, but Dr. Lantz did not believe that these allergies accounted for all of her ailments that began in September or October of 2001. Id. at 33.

In February of 2002, because they were getting no results and Kelley seemed to be getting sicker, the family started to see doctors at the Christie Pediatric Group. There were a series of doctor visits in February of 2002 during which time Kelley complained of a persistent cough, congestion, and fever. Id. at 45, 49, 53, 57. Several more office visits and phone calls prompted Kelley's doctors to order blood work, which was done in March of 2002, which tested normal. Id. at 63, 73,74, 84, 87, 88. The primary care physician they were seeing at that time "strongly pursued the emotional and psychological component a number of times during the discussion of

[Kelley's] history," to which Mrs. Armstrong took offense and ended the relationship. P. Aff. at 3-4; P. Med. Recs. at 87.

After several more consultations and tests in April of 2002, P. Med. Recs. at 94, 99, 103, on April 12, 2002, Mrs. Armstrong took Kelley for a consultation at the Duke University Medical Center. P. Aff. at 4. She was examined by an apparent neurologist, Dr. Nebbout, who found that "nothing was neurologically wrong with [Kelley]," but suggested that Kelley be seen by a rheumatologist. Id.[4] According to the petitioner, Dr. Nebbout "definitely felt there was a relationship to the vaccine and all [Kelley's] problems." Id.

They returned to Duke Medical Center on April 17, 2002, and sought the advice of Dr. Egla Rabinovich, a pediatric rheumatologist. P. Med Recs. at 113. After running a variety of tests, Dr. Rabinovich concluded that:

> In summary, Kelley has symptoms suggestive of fibromyalgia (generalized pain, sleep disturbance, fatigue and tenderpoints). However[,] on exam she also has findings of pain on tendon insertions and probable arthritis particularly on the left wrist. This [sic] findings suggest that she may have spondyloarthropathy with associated fibromyalgia.

Id. In her affidavit, Mrs. Armstrong points out that Dr. Rabinovich did not believe that Kelley's illness was related to the hepatitis B vaccine. P. Aff. at 4.

After her trip to Duke University, Mrs. Armstrong reports that Kelley continued to develop new and different symptoms, such as bulging and swollen eyes, and "chronic burping lasting hours and days." Id. Complaining that none of the medications were working, Mrs Armstrong contacted a chiropractor out of Utah who recommended some "vitamins/minerals/herbs" for Kelley. Id. at 5. Mrs. Armstrong slowly weaned Kelley off the prescribed medications and the symptoms "slowly respond[ed] to [the supplements] he recommended." Id.

On June 12, 2002, Kelley was again seen at the Duke Rheumatology Department for examination and follow-up with Dr. Laura Schanberg, at which time Dr. Schanberg reported that Kelley "had been doing well in the interval" since her last visit on April 17, 2002. P. Med. Recs. at 180. On July 22, 2002, Kelley attended a follow-up with her pediatrician.[5] Id. at 203. Mrs.

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[4]There were no medical records found in petitioner's submission regarding this visit. This information was gleaned from petitioner's affidavit.

[5]In her affidavit, Mrs. Armstrong reports that this follow-up occurred at Duke University Medical Center; however, the medical records reflect that this visit took place at Easley Pediatrics.
(continued...)

Armstrong advised the doctor that "after nutritional research and supplements she was doing really well." P. Aff. at 5. At this visit, Kelley was told that her fibromyalgia and rheumatoid arthritis were in remission. Id.; P. Med. Recs. at 203-04.

B. Expert Report

On December 10, 2004, petitioner filed a medical expert report by Dr. U. Evren Akin, MD. In addition, on April 11, 2005, Dr. Akin supplemented the report with an affidavit, both of which reflect Dr. Akin's opinion regarding Kelley's injuries. See P. Exp. Rep.; Appx. at 64-66.

Dr. Akin is a board-certified pediatric rheumatologist.[6] P. Ex. Rep. at 1. In the expert report and affidavit filed, Dr. Akin opines to a medical degree of certainty that Kelley Armstrong developed seronegative enthesopathy-arthropathy subtype of juvenile spondyloarthropathy in association with an immune reaction to the hepatitis B vaccination that occurred on July 16, 1999. Id. at 1-2; Appx. at 64. Dr. Akin bases her opinion on a "comprehensive, retrospective review of [Kelley's] medical records from before and after the receipt of the Hepatitis B vaccine, her school records, the pertinent medical literature and my education, training and experience as a pediatric rheumatologist." Appx. at 64.

In her expert report, Dr. Akin describes juvenile spondyloarthropathies as a "group of clinical conditions and diseases of entheses (point of insertion of tendon, ligament, joint capsule or fascia to bone) and synovium of the joints, tendon sheets, and bursae that predominantly involve the lower extremities of children." P. Ex. Rep. at 3. Furthermore, Dr. Akin explains that these diseases are distinguished from juvenile rheumatoid arthritis by criteria that include the waxing and waning nature of the disease, involvement of the entheses, as well as extraarticular involvement. Id. Dr. Akin continues that "[t]he disease course is characterized by frequent remissions and exacerbations, making the diagnosis difficult," noting that in Kelley's case it took several years to make such a diagnosis. Id. at 3-4. Dr. Akin then opines as to why it took so long for doctors to determine that Kelley Armstrong suffered from this illness:

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[5](...continued)
See P. Med. Recs. at 203-04.

[6]Dr. Akin received her medical degree from the Medical Faculty of Istanbul University in Turkey. She completed an internship and residency in pediatrics at Massachusetts General Hospital at Harvard Medical School in Boston, Massachusetts. Relating to the field of rheumatology, Dr. Akin completed a fellowship in pediatric rheumatology at Tufts University's Floating Hospital for Children and also was a research fellow at Beth Israel Hospital at Harvard Medical School. Currently, Dr. Akin is a member of the University of Minnesota School of Medicine in the department of pediatrics. She is also on staff at the Gillette Children's Specialty HealthCare in St. Paul, Minnesota. P. Ex. Rep. at 1.

> Enthesitis is quite difficult to diagnose since physicians who are not pediatric rheumatologists will often not know how to do this exam. It is also difficult to diagnose because it does not always go along with arthritis; hence physicians may not examine the patient further when they cannot find arthritis.

Id. at 4. With respect to Kelley's situation, Dr. Akin believes that Kelley's symptoms **began within days** of the vaccine and continued in a mild form for nearly 35 months after seemingly remitting for a year or year and a half. Id. at 5. Furthermore, Kelley did not have any symptoms of spondyloarthropathy before the vaccine. Id. Dr. Akin also points out that the waxing and waning of the disease is "typical" and lack of medical records or physicians' notes "should not be construed as unsupportive of this diagnosis." Id. She notes that the "the very nature of this condition is that it has an insidious onset," and that medical providers often attribute complaints of joint aches and pains as "growing pains." Appx. at 65 (Affidavit of U. Evren Akin, MD). In fact, the medical records show that none of Kelley's treating doctors were suspicious or aware that the discomfort that she was experiencing was due to SEA until April 2002. Id. Making the diagnosis even more difficult in Kelley's case was that she also had "confounding conditions (seasonal allergy, fibromyalgia, depression) that further obfuscated her medical picture." Id. It was not until two highly respected pediatric rheumatologists observed Kelley's entire medical history in which "sufficient pieces of the puzzle were available for them to determine she had SEA." Id. at 66.

ANALYSIS

At issue in this ruling is whether petitioner filed her petition for compensation within the statutorily prescribed period of the Vaccine Act. The statute of limitations provision of the Act applicable in this case, § 16 (a)(2), states:

> [A] vaccine set forth in the Vaccine Injury Table which is administered after the effective date of the subpart, if a vaccine-related injury occurred as a result of the 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. . . .

As stated earlier, petitioner, relying heavily on the Setnes court's interpretation of § 16(a)(2), asserts that her claim was filed within the applicable 36 month period. The undersigned has reviewed the entire record as well as the briefs by the parties. Contrary to the petitioner's arguments and consistent with respondent's position, the undersigned believes that the facts of this case fall within the parameters of the Court of Appeals for the Federal Circuit's decision in Brice v. Secretary of Health and Human Services, 240 F.3d 1367 (Fed. Cir. 2001), which the undersigned is obliged to follow. Relying on Brice, the undersigned finds that petitioner has not

filed her petition within the statute of limitations period, and thus the petition is jurisdictionally barred. A full discussion regarding this analysis follows.[7]

Petitioner's expert states clearly that Kelley's onset of joint pain began within days after her July 16, 1999 hepatitis B vaccination. P. Ex. Rep. at 5, 6-7. Thus, a petition to be timely should have been filed by no later than July 2002.[8] Given that the petition was filed on May 28, 2003, the petition's filing was clearly outside the allowable 36 month statute of limitations period and is thus jurisdictionally barred.

In making this determination, the undesigned relies upon settled jurisprudence from the Court of Appeals for the Federal Circuit, namely that court's decision in Brice. In Brice, the Circuit was presented with the question of whether equitable tolling principles could extend the statute of limitations period under the Act. The Circuit found that the doctrine of equitable tolling does not apply to cases filed after the Act's effective date, so-called Post-Act cases. Brice, 240 F.3d at 1372. While equitable tolling is not the issue in the case at bar, the Brice court's reasoning in resolving the equitable tolling issue does have application.

The facts of Brice are similar to those involved in this case, and for that matter, similar to many of the vaccine cases filed under the Program. In Brice, petitioners filed a petition on December 19, 1995, seeking compensation for injuries that their child allegedly suffered from the measles, mumps, and rubella vaccine [hereinafter "MMR vaccine"]. The Brices' child received his first vaccination on April 30, 1992. Id. at 1369. Nine days later, the child suffered a seizure, which petitioners at that time did not associate with the vaccination, but later contended signified the first manifestation of a vaccine-related injury. Id. Subsequent to the seizure, petitioners' child experienced developmental delays. Id. The treating neurologist diagnosed the child with a

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[7]Petitioner also relies on Massard, 25 Cl. Ct. at 424, see *supra* p. 3, asserting that this case stands for the proposition that accrual of an injury begins on the date that petitioner discovers he or she has been injured, not on the date in which the wrong occurs. Presumably, petitioner argues that along this line of reasoning, the accrual of the statute of limitations began when Kelley discovered that she had an injury in April of 2002 – not when she began experiencing symptoms a few days post-vaccination.

The undersigned finds that petitioner's reliance on this case is misplaced. First, the portion of the decision that is cited by petitioner is a discussion by Judge Harkins of the application of tolling principles in private litigation involving the Age Discrimination in Employment Act, 29 USC §§ 621 et. seq. More importantly, it is well settled law that under the Vaccine Act, "the statute of limitations [] begins to run upon the first symptom or manifestation of the onset of injury, *even if the petitioner reasonably would not have known at that time* that the vaccine had caused an injury." Brice, 240 F.3d at 1373 (emphasis added).

[8]It is not critical to the determination here to find the exact date since petitioner's filing is far beyond the applicable three-year period.

residual seizure disorder and informed the parents that the MMR vaccine may have caused the disorder. Id. The doctor suggested that the Brices file a claim under the Vaccine Act. Id. It was at this March 30, 1995 appointment that the Brices first associated the vaccine with their child's injuries. Id. After seeking information about the Vaccine Act and obtaining medical records, the Brices filed their claim pro se on December 19, 1995. Id.

The Brice case dealt primarily with the question of whether § 16(a)(2) is subject to equitable tolling. The Federal Circuit found that it is not. Id. at 1374. Relevant to the case at hand is the court's discussion of the statute of limitations period. The court pointed out that the statute of limitations period began to run in Brice with the first seizure of May 9, 1992, nine days post-vaccination. Id. at 1369 n.1. Thus, the period for filing the petition expired on May 9, 1995. Critical to the case at bar is the court's finding related to the doctor's diagnosis of a residual seizure disorder and notification to the parents of the vaccine's potential causative role. The court stated:

> In addition, we note that the statute of limitations here begins to run upon the first symptom or manifestation of the onset of injury, **even if the petitioner reasonably would not have known at that time that the vaccine had caused an injury.**

Id. at 1373 (emphasis added). The court continued discussing this lack of parental awareness as it related to equitable tolling stating further that:

> It would be quite odd for Congress to allow a **limitations period to run in cases in which a petitioner has no reason to know that a vaccine recipient has suffered an injury**, but to provide for equitable tolling when a petitioner is aware that a vaccine has caused an injury but has delayed filing suit.

Id. (emphasis added). Thus, a reasonable interpretation of the Federal Circuit's language is that the statute of limitations runs from the objective first symptom or manifestation of onset, not the parents subjective knowledge, date of association with the vaccine, diagnosis, or doctor's confirmation.

Kelley Armstrong's case fits squarely into Brice. Petitioner reported in her affidavit that she felt that "something had gone wrong due to the vaccine" when Kelley had what petitioner "knew" was a seizure a few minutes after the vaccination. P. Aff. at 1. Although Dr. Akin stated that "[t]he diagnosis and relation back to the Hepatitis B vaccination was not possible until April of 2002," when the doctors at Duke University Hospital "synthesized all of Kelley's complaints and symptoms since July of 1999," P. Ex. Rep. at 7, consistent with petitioner's affidavit, Dr. Akin opined that Kelley's "medical records clearly document the onset of joint pain within days after the Hepatitis B vaccination." Id. at 6-7.

Based upon the petitioner's affidavit and Dr. Akin's opinion that Kelley's symptoms began within days following the July 16, 1999 vaccination, the petition had to be filed by July 2002 to comply with § 16(a)(2). The petition was filed on May 28, 2003, far beyond the 36 month period. Applying Brice's teachings leads to the inescapable conclusion that petitioner's May 28, 2003 filing was beyond the allowable 36 month period and is thus jurisdictionally barred.

In so finding that petitioner has filed beyond the Act's statute of limitations, the undersigned has studied the Setnes opinion relied upon by petitioner and finds it to be inapposite.[9] In Setnes, the parents testified that after their son, AJ's, September 11, 1998 vaccinations, AJ's behavior began to change. Setnes, 57 Fed. Cl. at 176. For instance, he started to make a constant humming noise, was doing a lot of babbling, was slow to develop words, and would no longer respond to his name after a period of time. Id. at 176-77. He started to have temper tantrums, would kick and scream, and was sometimes inconsolable. Id. at 177. The Setneses also noticed that AJ would run around the kitchen table and just stare at the edge of the table or counter. Id. He would eat cardboard boxes that held videotapes and eventually stopped making eye contact with his family members. Id. His speech development also continued to be delayed. Id.

After expressing concern about these behaviors to their pediatrician on a July 16, 1999 visit, the Setneses' pediatrician noted that the behaviors may be indicative of pervasive developmental disorder [hereinafter "PDD"]. Id. Following a January 7, 2000 examination, the doctors described AJ as having "'probable PDD/autism,'" which led to a formal diagnosis of autism on March 3, 2000. Id. However, the Setneses did not file their petition until July 15, 2002,

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[9]In her response to respondent's motion to dismiss, petitioner argues that Setnes is binding on the special master because "[t]he Court of Federal Claims has the express jurisdiction to review any decision by the Office of Special Masters, a lower level judicature, and to overturn any decision found to be arbitrary, capricious or not in accordance with the law." P. Res. at 10 n.1. Petitioner continues that "[f]irst year law students learn that a decision by a court of higher level in the same jurisdiction will have precedential effect over decisions by a lower tribunal in that jurisdiction." Id. Petitioner is incorrect in her assertion. It is well settled law that the special masters are not bound by decisions by the Court of Federal Claims judges unless the decision is on remand in the same case. Hanlon v. Secretary of Health and Human Services, 40 Fed. Cl. 625, 630 (1998), *aff'd*, 191 F.3d 1344 (Fed. Cir.1999), *cert. denied sub nom.* Hanlon v. Shalala, 530 US 1210 (2000). As has been recognized, Setnes presents legal issues that will have to be addressed by the United States Court of Appeals for the Federal Circuit. See Markovich v. Secretary of Health and Human Services, No. 03-2015V, 2005 WL 3112410 at *8, *appeal docketed*, No. 06-5039 (Fed. Cir. Dec. 27, 2005); James-Bey v. Secretary of Health and Human Services, No. 05-10V, slip. op. at 6 n.2 (Fed. Cl. Aug. 8, 2005) (unpublished) (available at www.http://www.uscfc.uscourts.gov/unpublished%20decisions.htm). The Federal Circuit's rulings on these issues will be binding on the lower courts.

which respondent contended was filed one month out of time because the onset of AJ's symptoms occurred sometime between September 1998 and June 1999. Id. The Setneses argued that their petition was filed in time because it was filed within 36 months of the pediatrician's July 16, 1999 notation regarding PDD. Id. Relying on Brice, the special master dismissed the petition as filed seven months too late, relying on the testimony of petitioner's own expert, Dr. Donald Marks, MD, PhD, that symptoms of AJ's disorder began to appear by December 11, 1998. A motion for review was then filed by the petitioners. Id.

On appeal, Judge Futey reversed the special master's decision and found that the petition was filed within the 36 month period because "[b]ased on the contemporaneous medical evaluations and notations, AJ's onset of autism became evident between July 16, 1999 and January 7, 2000." Id. at 181. In dismissing Dr. Marks expert opinion that symptoms of autism began to occur within the three-month period following the September 11, 1998 vaccinations, Judge Futey reasoned that:

> As distinguished from other medical conditions, . . . the beginning stage of autism cannot be reduced to a single, identifiable symptom. Many of the initial "symptoms" are subtle and can easily be confused with typical childhood behavior. Where 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."

Id. at 179 (citations omitted).

Judge Futey focused on the insidious onset of autistic symptoms which may go unrecognized by parents and treating doctors and instead relied upon the point when the symptoms became "evident" to the treating doctors. Id. at 177. However, in so finding, Judge Futey went to some length to distinguish his finding from the cases "where the symptoms or the injury [were] clearly apparent." Id. at 181. Specifically, he stated that:

> The court is not holding that a medical or psychological diagnosis or verification of the "occurrence of the first symptom or manifestation of onset" begins the running of the statute of limitations . . . Rather in a situation such as that before the court, **where the symptoms of autism develop "insidiously over time"** and the child's behavior cannot readily be connected to an injury or disorder, the court may rely on the child's medical or psychological evaluations for guidance in ascertaining when the "manifestation of onset" occurred.

Id. (citations omitted) (emphasis added). In making this finding, Judge Futey distinguished the facts of two cases decided by the Court of Federal Claims prior to Brice, Childs v. Secretary of Health and Human Services, 33 Fed. Cl. 556 (1995) and Goetz v. Secretary of Health and Human

Services, 45 Fed. Cl. 340 (1999), *aff'd*, 4 Fed. Appx. 827 (Fed. Cir. 2001) (unpublished). Judge Futey reasoned that each of those cases involved "obvious" symptoms following vaccination and distinguished them from the facts of Setnes as follows:

> It is one thing to be unaware that an injury that an obvious injury or its onset was caused by a vaccination. It is quite another to lack knowledge, through no assignable fault, of the existence of the onset.

Setnes, 57 Fed. Cl. at 181.

In the case at hand, while it may be true as Dr. Akin states that the "diagnosis and relation back [of Kelley's spondyloarthropathy] to the Hepatitis B vaccine was not possible until April 2002," P. Ex. Rep. at 7, it is equally true that Mrs. Armstrong recognized and reported that Kelley reacted to her hepatitis B vaccination immediately following the immunization. P. Aff. at 1. As stated above, Mrs. Armstrong related in her affidavit that Kelley began feeling the effects of the alleged reaction when she had a seizure a few minutes after the vaccination. Id. While medical personnel did not believe that the events were caused by the vaccination, a VAERS report was filed. See P. Med. Recs. at 14.

In addition, several days following her vaccination, on July 19, 1999, Kelley was seen by Dr. Michelle Lynch at the Children's Medical Center for three seizure "episodes" that occurred on the day of the vaccination approximately ten minutes after she received her vaccination, each seizure lasting about three minutes. Id. at 5. As of July 19, Kelley had not had any other symptoms except for a left temporal headache, which she complained of intermittently. Id. at 6. At the request of her doctor, Kelley had a brain MRI and an EEG, which were normal. Id. at 10-11. Out of an abundance of caution, even though Dr. Lynch had a low suspicion that seizures were related to the vaccine per se, Kelley received an exemption from receiving hepatitis B vaccinations in the future. Id. at 3, 7.

Symptoms seemingly worsening, Kelley consulted with an allergist, Dr. Andrea Lantz, MD, on January 17, 2002. Id. at 34. According to Dr. Lantz's "Initial Summary," Kelley's chief complaints were headaches, cough, and dizziness. Id. Dr. Lantz also indicated, per Kelley's parents, that "**Kelley had been a normal healthy child until approximately eighteen months ago when she received the Hepatitis B vaccine.**" Id. (emphasis added). According to Kelley's parents, Dr. Lantz noted that she has had "declining health" since that time. Id. After tests and an examination, Dr. Lantz diagnosed Kelley with allergies to "two tree pollens, one weed pollen, and one mold." Id. at 33. Dr. Lantz believed, however, that "this can [not] account for all of her symptoms that began in September or October." Id.

Getting no results from Dr. Lantz's diagnosis, Kelley's parents then consulted with specialists at Duke University Medical Center. On April 17, 2002, Kelley was evaluated by Dr. Egla Rabinovich, MD, a pediatric rheumatologist. Id. at 113. It was at that visit that Kelley was formally diagnosed as having

> symptoms suggestive of fibromyalgia (generalized pain, sleep disturbance, fatigue and tenderpoints). However[,] on exam she also has findings of pain on tendon insertions and probable arthritis particularly on the left wrist. This [sic] findings suggest that she may have spondyloarthropathy with associated fibromyalgia.

Id.[10]

While the ultimate diagnosis of Kelley's symptoms took time, Mrs. Armstrong showed by the filing of a VAERS report and her multiple discussions with doctors that she was aware of Kelley's symptoms of injuries and also of a temporal association with the hepatitis B vaccine. Thus, this case fits squarely within the facts of the Brice, Childs, and Goetz line of cases, and assuming it is correct, does not meet the exception carved out in Setnes.

Lastly, as noted earlier, the correctness of the Setnes decision is yet to be determined by the Federal Circuit. See *supra* note 9. However, one aspect of the Setnes court's reasoning bears

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[10]In fact, with the diagnosis in April of 2002, see P. Med. Recs. at 113, 118-19, petitioner still had time to file her petition but failed to do so. It is clear from petitioner's affidavit that she recognized at that time that there was a potential relationship between the vaccine and Kelley's injuries. Per her purported discussions with Dr. Nebbout at Duke University on April 12, 2002, Mrs. Armstrong stated that Dr. Nebbout "definitely felt there was a relationship to the vaccine and all [Kelley's] problems." P. Aff. at 4. In addition, Mrs. Armstrong admitted in her affidavit that on or around February 2002, fully four months prior to the running of the statute of limitations, she

> completed a form for Kelley on the Internet thinking I was filing a claim of injury due to the Hepatitis B Vaccine. Unfortunately, when I contacted the National Vaccine Information Center early May 2003, they had no record on file of a claim for Kelley. They asked me some questions about what I filled out and asked if I had any copies. Unsure, I said I would call back. I dug through papers first and found nothing and then retraced my steps on the Internet to find the form I submitted. I found something similar to the form and was so disappointed to find it was a report of injury form. The form had stated, "Please use this form to report to the National Vaccine Information Center."

Id. at 6. Unfortunately for petitioner, the court cannot remedy this mistake.

comment.[11] With all due respect to the Setnes court, in the undersigned's analysis, the Setnes court should not have rejected petitioner's expert's opinion because of its retrospective nature. Thus, in rejecting the application of the "occurrence of the first symptom" standard, Judge Futey accepted Dr. Larsson's, a PhD, not a qualified MD, description in an affidavit of the beginning stages of autism as subtle symptoms not capable of being reduced to a single, identifiable symptom. Setnes, 57 Fed. Cl. at 180. Accordingly, with no "clear start" to the injury, Judge Futey found "prudence" dictates rejection of the "occurrence of the first symptom" standard. Id. at 179. However, petitioner's own expert, Dr. Marks, an MD and PhD, contended that the symptoms began within three months following vaccination. Id. at 177. Thus, Dr. Marks was able to identify symptoms of onset which may or may not meet the "occurrence of the first symptom" standard. However, that evidence was not considered fully. The Setnes court rejected Dr. Marks' opinion out-of-hand because it was

> rendered over two years after AJ's official diagnosis, [and] was the product of a **retroactive evaluation and enjoyed the benefit of hindsight.** In other words, Dr. Marks had the fully assembled puzzle in front of him, and when taking the puzzle apart, opined that the pieces he was taking apart must have come from the puzzle. Dr. Marks' retroactive diagnosis is plainly inconsistent with AJ's contemporaneous medical evaluations.

Id. at 180 (emphasis added). The court found Dr. Marks' opinion inconsistent with the medical records because AJ's pediatricians did not recognize the signs of autism until a later point in time. Id. at 181. But, as has been seen by the undersigned in countless cases, it is possible that the pediatricians did not have the opportunity to recognize earlier the signs, did not have the requisite expertise to recognize the early signs of autism, or simply missed the early signs; or, it is possible that Dr. Marks is incorrect. The critical point is that the determination of what evidence is credible and which is not should come only after weighing **all** of the evidence.

In resolving vaccine cases, the decision maker is obliged to consider the entire record. § 13(a); Pafford v. Secretary of Health and Human Services, 64 Fed. Cl. 19, 30 (2005), *appeal docketed*, No. 05-5106 (Fed. Cir. Apr. 12, 2005); Gamache v. Secretary of Health and Human Services, 27 Fed. Cl. 639, 645 (1993), *aff'd*, 5 F.3d 1505 (Fed. Cir. 1993) (unpublished). A critical part of that record is the expert's analysis of the case. In the undersigned's experience, in fact, in well over 50% of the cases, it is the expert's retrospective analysis that provides the

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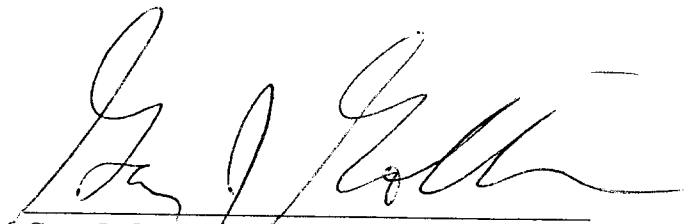
[11]Both petitioner and respondent make legal arguments opining as to what is the "appropriate" interpretation of the statutory terms "first symptom or manifestation of onset." § 16(a)(2); see P. Res. at 8-10, Motion at 11-17. The undersigned refrains from discussing this issue because the undersigned's decision does not hinge on the interpretation of this particular part of the Act. Rather, as described above, the undersigned finds that the Federal Circuit's decision in Brice is applicable to the facts as presented in the case at bar, and is obliged to follow that precedent.

critical evidence undergirding the decision. The typical case record includes medical records and parents' affidavits providing factual information, the treating doctors' contemporaneous analyses of patient histories and the medical tests which provide the treating doctors' perspective of the patient's case, and both petitioner's and respondent's experts re-evaluating the facts and contemporaneous medical tests and interpretations thereof in offering their respective opinions. It must be noted that the weighing of this type of evidence, including retrospective reviews by experts, is done on a daily basis in countless instances in the Program and benefits predominantly petitioners, as the medical records are generally devoid of discussing a vaccine relationship to the injury. The consideration of retrospective analyses by experts as part of the evidentiary record has been accepted routinely by petitioners and the respondent alike, as well as by the courts in deciding these cases.

In Setnes, Dr. Marks, if given the chance, may not be able to convince the court that the early symptoms he saw were in fact "identifiable" and "evident." But the fact that he provided the analysis retrospectively, in the undersigned's view, is not sufficient grounds by itself for rejection. In the case at hand, Dr. Akin used the same retrospective analysis for her opinion. In fact, Dr. Akin described the diagnosis of SEA as one of "retrospection." Appx. at 64-66 (Affidavit of U. Evren Akin, MD). She describes the diagnostic process of the treating doctors at Duke as "looking retrospectively at [Kelley's] medical history since 1999" before "sufficient pieces of the puzzle were available for them to determine [Kelley] had SEA." Id. at 65-66. There is nothing inherently faulty with retrospective medical analysis and diagnosis. It is a process utilized by treating doctors and experts alike. It is not to be accepted blindly, but is to be weighed with other evidence in making legal determinations. However, when the unrebutted evidence of petitioner's expert places the timing of onset outside the statute of limitations period, the undersigned finds that evidence to be highly probative on that issue. See Markovich, 2005 WL 3112410 at *7 (affirming special master's reliance on expert testimony notwithstanding the benefit of "hindsight").

In this case, unfortunately for petitioner, her claim was filed beyond the 36 month period. This is because the medical records and petitioner's own expert establish that the symptoms Kelley had days after the vaccine were related to her current condition. The undersigned is thus constrained to grant respondent's motion and dismiss the petition as untimely.

IT IS SO ORDERED.



Gary J. Golkiewicz
Chief Special Master