ORIGINAL

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 03-2755V
Filed: July 25, 2014

* *

VALE KRENIK, parent of V.K., a minor,

Petitioner,

v.

SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Autism; Statute of Limitations; Untimely Filed

Vale Krenik, Plano, TX, *pro se* petitioner.[1]
Linda Renzi, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

DECISION[2]

Vowell, Chief Special Master:

Vale Krenik ["petitioner"] filed a "Short-Form" petition for vaccine compensation[3] under the National Childhood Vaccine Injury Act[4] ["Vaccine Act"]

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[1] Mr. Krenik is an attorney licensed to practice in Texas, as reflected by his Texas bar number on his filings.

[2] Because this decision will be published, in accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[3] By electing to file a Short-Form Autism Petition for Vaccine Compensation, petitioner, who was then represented by counsel, alleged that:

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

on behalf of his son, V.K., on December 1, 2003.[5] No medical records were filed with the petition. Based on the "short form" petition, the case was included in the Omnibus Autism Proceeding ["OAP"], and, in effect, stayed until litigation of the test cases was completed.[6]

I. Procedural History.

After resolution of the OAP test cases,[7] petitioners in OAP cases were asked if they wished to proceed with or dismiss their claims.[8] On December 21, 2012, petitioner's counsel filed a motion asking that he be permitted to withdraw as attorney of record because he believed there was no reasonable basis to

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Autism General Order #1, filed July 3, 2002, Exhibit A, Master Autism Petition for Vaccine Compensation at 2 which can be found on the court's website at http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf.

[4] 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-10 et seq. (2006). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

[5] Custody of V.K. is shared between his parents. *See* Petitioner's Exhibit ["Pet. Ex."] 3, pp. 130-64 (V.K.'s parents' final divorce decree filed as part of V.K.'s pediatric records). V.K.'s mother has not joined in the vaccine injury claim. *See* Letter, filed into the record by Special Master Hastings on Nov. 10, 2005 [Docket Event 10].

[6] *See* Notice, issued Jan. 8, 2004, at 1-2 (The OAP was "a general inquiry by the Office of Special Masters ("OSM") regarding the possible causal relationship between certain vaccinations . . . and autistic spectrum disorders or similar neurodevelopmental disorders."). Proceedings in the other cases in the OAP were stayed pending the outcome of the test case litigation.

[7] The Petitioners' Steering Committee ["PSC"], an organization formed by attorneys representing petitioners in the OAP, litigated six test cases presenting two different theories on the causation of Autism Spectrum Disorders ["ASDs"]. Decisions in all six cases rejected petitioners' causation theories. The Theory 1 cases are *Cedillo v. Sec'y, HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y, HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y, HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009). Petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims. The Theory 2 cases are *Dwyer v. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y, HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y, HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). The petitioners in each of the three Theory 2 cases chose not to appeal.

[8] Because the attorney then representing petitioner had a large number of OAP cases, he was allowed to work with the petitioners in his cases on an extended timetable to determine if they wished to continue with their claim, resulting in a delay in ascertaining whether Mr. Krenik wished to proceed with V.K.'s case.

continue with the claim.[9] Motion at 5-6. Respondent's counsel opposed this request. First Response, filed Jan. 9, 2013. In her response (*id.* at 1 n.2) as well as her response to counsel's interim fee request (Second Response, filed Jan. 9, 2013, at 2-3), respondent argued that petitioner's claim was not timely filed, although she did not make a formal motion to dismiss it.

The case was reassigned to me on March 8, 2013. In response to my March 21, 2013 order, petitioner's counsel filed some medical records on April 22, 2013. *See* Pet. Exs. 1-4. I then granted his request to withdraw and ordered Mr. Krenik (now a *pro se* petitioner) to file all medical records from V.K.'s birth to five years of age. Order, issued May 1, 2013, at 1-2. I also cautioned petitioner that the case appeared to be untimely filed. *Id.* at 3. Mr. Krenik requested additional time and a status conference. Motion, filed July 5, 2013, at 1.

I held a digitally-recorded telephonic status conference on August 1, 2013. Linda Renzi appeared on behalf of respondent, and *pro se* petitioner Vale Krenik was present on the call. During the call, I explained that after V.K.'s medical records were filed, certain threshold issues, such as whether the case was timely filed, needed to be addressed. Order, issued Aug. 5, 2013, at 1. Since petitioner informed me that he had experienced difficulty obtaining V.K.'s medical records, I ordered him to file a list of all medical facilities so I could authorize subpoenas to collect any missing medical records. *Id.* at 2.

Petitioner filed medical records on December 26, 2013. *See* Pet. Exs. 5-15.[10] He also filed a status report indicating problems with some of the medical records and requesting an additional thirty days "to complete authentication of records as well as any witness statements." Status Report, filed Dec. 26, 2013, at 1-2. On January 28, 2014, he filed more medical records, some additional test results from 2002 and 2003 and an additional copy of V.K.'s autism diagnosis (also filed as Pet. Ex. 5). *See* Pet. Exs. 16-18.[11]

The filed records clearly reflect that symptoms of autism were present more than thirty-six months before the petition was filed. Explaining that the evidence filed did not demonstrate either "that this case was timely filed . . . [or]

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[9] Petitioner's counsel also requested interim attorneys' fees and costs. Respondent objected to the award due to its interim nature and the fact that she believed the case to be untimely filed. Second Response, filed Jan. 9, 2013, at 2-3. After deferring my ruling until the Supreme Court issued its decision in *Sebelius v. Cloer*, 133 S.Ct. 1886 (2013), I awarded interim attorneys' fees and costs. *See* Decision, issued Jan. 7, 2014.

[10] Petitioner labeled these medical records as Pet. Exs. 5-14 and A. I redesignated Pet. Ex. A as Pet. Ex. 15 on January 24, 2014.

[11] Because Mr. Krenik may not have received my January 24, 2014 Order redesignating Pet. Ex. A as Pet. Ex. 15 before he filed these additional medical records, he used exhibit numbers 15-17. I redesignated these exhibits as Pet. Exs. 16-18. *See* Show Cause Order, issued Feb. 4, 2014, at 3 n.9.

any extraordinary circumstances warranting equitable tolling," I ordered petitioner to show cause why the petition should not be dismissed as untimely filed. Show Cause Order, issued Feb. 4, 2014, at 5.

Petitioner filed his response on March 6, 2014, asserting that the Centers for Disease Control and Prevention ["CDC"] intentionally altered and denied access to information which would prove a link between autism and thimerosal in vaccines. Petitioner's Response ["Pet. Response"] at 5. Petitioner argues "that the statutory construction [of the Vaccine Act] needs to be re-evaluated to allow a discovery rule [and] that grounds exist for both equitable tolling and equitable estoppel . . . to extend the statute of limitations." *Id.* at 1.

I ordered respondent to file a reply to petitioner's response. Respondent filed her reply on March 25, 2014, arguing that petitioner's assertions are unfounded and false and that, even if true, "petitioner never explains how the alleged fraud prevented him from timely filing his claim." Respondent's Reply ["Res. Reply"] at 3. Respondent maintains "[t]he Federal Circuit has made clear that there is no explicit or implied discovery rule under the Vaccine Act . . . [and] held that equitable tolling is not a substitute for the discovery rule." *Id.* at 3-4.

After examining all of petitioner's arguments, I reject petitioner's assertion that the Vaccine Act contains a discovery rule and find nothing to warrant an application of equitable tolling or equitable estoppel in this case. Having considered the record as a whole, I find that the petition was filed after the expiration of the Vaccine Act's statute of limitations, and that it must, therefore, be dismissed.

II. Statute of Limitations.

The Vaccine Act provides that:

> In 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 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 . . . .

§ 16(a)(emphasis added).

The Court of Appeals for the Federal Circuit has interpreted this statutory language, affirming that the statute of limitations begins to run on "the date of occurrence of the first symptom or manifestation of onset of the vaccine-related

injury recognized as such by the medical profession at large." *Cloer v. Sec'y, HHS*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc) ["*Cloer III*"]. The Circuit explained that this date is "a statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition." *Id.* at 1339. The date is dependent on when the first sign or symptom of injury appears, not when a petitioner discovers a causal relationship between the vaccine and the injury. *Id.* at 1339-40.

Although the Federal Circuit found that equitable tolling was not warranted in *Cloer*, it held that Congress did not create an exemption in the Vaccine Act to the rebuttable presumption articulated in *Irwin v. Dep't of Veteran Affairs*, 498 U.S. 89, 95-96 (1990), that equitable tolling applies to a federal statute of limitations. *Cloer*, 654 F.3d at 1340-44 (overruling *Brice v. Sec'y, HHS*, 240 F.3d 1367 (Fed. Cir. 2001)).

III. Analysis.

A. First Symptom or Manifestation of Onset.

To be timely filed under the Vaccine Act's statute of limitations, this claim must have been filed within 36 months from the date of the occurrence of "the first symptom or manifestation of onset or of the significant aggravation" of V.K.'s autism. § 16(a)(2). Since the petition was filed on December 12, 2003, it is untimely filed if V.K. exhibited symptoms of autism prior to December 12, 2000.

Although V.K.'s records are not complete, the filed records establish that V.K. exhibited symptoms of autism as least as early as June 2000. According to an entry in his pediatric records, V.K.'s autism symptoms began when he was two years old. *See* Pet. Ex. 14, p. 173. V.K. was two years old from mid-June 1999 until mid-June 2000, as he was born in mid-June 1997; thus, symptoms of autism likely existed, at the very least, six months prior to December 2000.

Moreover, V.K. was diagnosed as "within the severely autistic range" on November 1, 2000. Pet. Ex. 5, p. 4. At the evaluation that led to the diagnosis, Mr. Krenik indicated that V.K. had been displaying numerous symptoms of autism.[12] He reported that he was "not sure that [V.K.] ever made good eye contact." Pet. Ex. 5, p. 2. He recounted that he became concerned when V.K. "was not developing language other than 'parroting'[13] what he heard." Pet. Ex. 5, p. 2. He described behaviors of dropping objects over and over again, not liking things to be out of place, enjoying certain textures, not responding to pain, and a fear of certain noises (*id.*, p. 3), all of which are recognized as symptoms of

[12] *See White v. Sec'y, HHS*, No. 04-337V, 2011 WL 6176064, at *4-9 (Fed. Cl. Spec. Mstr. Nov. 22, 2011) (describing symptoms of autism).

[13] "Parroting" is another word for "echolalia," the "stereotyped repetition of another person's words or phrases." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32d ed. 2012) at 589. Echolalia is an autism symptom. *White*, 2011 WL 6176064, at *7.

autism.

The evaluator, Denise McCallon (Ph.D.), was unable to complete her assessment of V.K.'s development due to his inability to engage or imitate, and his inattentiveness, but concluded that his behavior was unmistakably autistic. Pet. Ex. 5, p. 4. His score of 41.5 on the Childhood Autism Rating Scale,a diagnostic test for autism, placed him in the "severely autistic range." *Id.*

In her report, Dr. McCallon referenced an earlier evaluation at the Park Cities Speech, Language, and Hearing Center, showing V.K. was diagnosed with "[a] severe speech and language disorder" in August 2000. Pet. Ex. 5, p. 3 (quotations omitted). As the Federal Circuit noted in *Carson*, speech delay qualifies as "the first objectively recognizable symptom of autism." *Carson ex rel. Carson v. Sec'y, HHS*, 727 F.3d 1365, 1370 (Fed. Cir. 2013). During this earlier speech evaluation, V.K. also exhibited "poor eye contact, . . . echolalia, [and] minimal direction following," all symptoms of autism. Pet. Ex. 5, p. 3; *see White,* 2011 WL 6176064, at *4-9 (explaining that poor eye contact, echolalia, and inability to follow directions are symptoms of autism).

In summary, the medical records show that V.K. exhibited numerous symptoms of autism prior to December 12, 2000. There is evidence that V.K.'s first symptom or manifestation of onset occurred on or before June 2000, and certainly by August 2000. Thus, the petition was filed months after the expiration of the Vaccine Act's statute of limitations.

B. Petitioner's Arguments.

Petitioner is not challenging whether the symptoms described in my show cause order and discussed in Part A of this decision constitute symptoms of autism, nor when they first occurred. *See* Show Cause Order, issued Feb. 4, 2014, at 4-5; Pet. Response, filed Mar. 6, 2014. Instead, he relies on multiple factual and legal arguments to claim the petition was timely filed or, in the alternative, that equitable tolling and equitable estoppel are warranted. He also asserts that it was improper for me to raise, *sua sponte*, the issue of timeliness. He maintains that I did not provide him with an adequate opportunity to respond to my Show Cause Order, and he requests that I strike former counsel's statements regarding the viability of the claim. Each of petitioner's arguments is addressed below.

1. *Sua Sponte* Consideration of the Issue of Timeliness.

Petitioner asserts that it was error for me to issue my show cause order, *sua sponte*, and claims I have "provided argument appropriate for a Respondent" and "formulated an opinion on the matter prior to the completion of the final trial." Pet. Response at 5-6. It is unclear whether petitioner simply wants more time or whether he is actually arguing that I must conduct an entitlement hearing prior to

resolving whether the claim was timely filed, or both. He did not ask for more time to respond to the show cause order.[14] Therefore, I focus primarily on the issue of timely filing as a threshold issue.

Under the Vaccine Act, I am required to issue a decision which includes findings of fact and conclusions of law as expeditiously as possible. § 12(d)(3)(A). While conducting a proceeding, I may require evidence, information, testimony, and documentation. § 12(d)(3)(B)(i)-(iii). The Vaccine Act requires that I "afford all interested persons an opportunity to submit relevant written information" (§ 12(d)(3)(B)(iv)), but there is "no discovery in a proceeding on a petition other than the discovery required by the special master" (§ 12(d)(3)(B)).

I may conduct a hearing if reasonable and necessary (§ 12(d)(3)(B)(v)), but a hearing is not required. The Vaccine Rules[15] specifically state that I "may decide a case on the basis of written submissions without conducting an evidentiary hearing." Vaccine Rule 8(d). The written submissions "**may** include a motion for summary judgment, in which event the procedures set forth in RCFC 56[16] will apply" (Vaccine Rule 8(d) (emphasis added)), but there is nothing in the Vaccine Rules indicating a motion for summary judgment is required. Moreover, Rule 56 specifically indicates I may "consider summary judgment on its own after identifying for the parties material facts that may not be genuinely in dispute." RCFC 56(f)(3). This is precisely what I did in the show cause order.

Petitioner's argument is similar to the one advanced by the petitioner in *Reed v. Sec'y, HHS*, 69 Fed. Cl. 437, 440 (2005) (arguing that the dismissal for untimely filing "amounted to an improper use of summary judgment, in light of genuine issues of material fact"). Relying on the allegations as set forth in the petition, the special master in *Reed* determined the petition was filed after the expiration of the statute of limitations. *Reed v. Sec'y, HHS*, No. 05-575V, 2005 WL 6120643, at *3 (Fed. Cl. Spec. Mstr. Jul. 26, 2005). Judge Bruggink affirmed the special master's decision, holding that "[t]imely filing is a pre-condition to suit

[14] Although I issued the show cause order *sua sponte*, I note that respondent had previously raised the issue of untimely filing. As there is no genuine issue of material fact concerning when the symptoms of autism arose, and respondent had already raised the issue, the show cause order was an appropriate mechanism to require petitioner to demonstrate some exception to the statutory requirement for timely filing.

[15] The Vaccine Rules, which can be found at Appendix B to the Rules of the United States Court of Federal Claims ["RCFC"], govern all Vaccine Act proceedings. Vaccine Rule 1(a). If a matter is not specifically addressed by the Vaccine Rules, the special master of the court "may regulate the applicable practice, consistent with these rules and with the purpose of the Vaccine Act, to decide the case promptly and efficiently." Vaccine Rule 1(b). "The RCFC apply only to the extent they are consistent with the Vaccine Rules." Vaccine Rule 1(c).

[16] Rule 56 allows a party to file a motion for summary judgment at any time until 30 days after the close of discovery. RCFC 56(b). The moving party must show "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." RCFC 56(a).

. . . [and] subject to review at any point in the litigation." *Reed*, 69 Fed. Cl. at 440.

Although the Federal Circuit later held that the Vaccine Act's statute of limitations is not jurisdictional and equitable tolling of Vaccine Act claims is available,[17] to be compensated, petitioner's claim must be timely filed. Thus, considerations of judicial efficiency may dictate a ruling on the timeliness of petitioner's claim prior to addressing vaccine causation. *See, e.g., Tucker v. Sec'y, HHS*, No. 03-346V, 2004 WL 950012, at *1, 3-4 (Fed. Cl. Spec. Mstr. Apr. 15, 2004) (finding it proper to dismiss a petition as untimely filed even though the issue of vaccine causation was deferred, awaiting the outcome of the OAP test cases).

Petitioner misunderstands the active role given to special masters in order to expedite vaccine proceedings.[18] Setting forth "a procedure in the Vaccine Act to decide claims that placed special masters on the front lines" (*Snyder*, 88 Fed. Cl. at 712), Congress instructed the special master "to be vigorous and diligent in investigating factual elements necessary to determine the validity of the petitioner's claim." H.R. REP. No. 99-908, at 17 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6358. As the Federal Circuit noted, "the permissible scope of the special master's inquiry is virtually unlimited." *Whitecotton v. Sec'y, HHS*, 81 F.3d 1099, 1108 (Fed. Cir. 1996).

Congress created an informal program designed to "avoid hearings and dispose of cases quickly." *Boley*, 2008 WL 4615034, at *2. This push for an expedited conclusion is reflected in Vaccine Rule 5 which requires me to evaluate the parties' positions early in the proceeding. *See* Vaccine Rule 5(a). Because it appeared the petition in this case was filed after the expiration of the

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[17] *Cloer III*, 654 F.3d at 1341 n.9, 1344 (Fed. Cir. 2011) (en banc). Following that decision, the petitioner in *Cloer* sought attorneys' fees and costs, and the Federal Circuit held that petitioners in untimely filed cases are eligible for attorneys' fees and costs. *Cloer v. Sec'y, HHS*, 675 F.3d 1358, 1364 (2012) (en banc) ["*Cloer IV*"]. The Circuit remanded to the Court of Federal Claims for a determination of whether the petition was filed in good faith and there was a reasonable basis for the claim. *Id.*; *see* § 15(e)(1) (requiring good faith and a reasonable basis for an award of attorneys' fee and costs for unsuccessful claims). The Supreme Court affirmed the Federal Circuit's decision, holding that an untimely filed petition "may qualify for an award of attorney's fees if it is filed in good faith and there is a reasonable basis for its claim." *Sebelius v. Cloer*, 133 S.Ct. 1886, 1896-97 (2013).

[18] *See Jane Doe v. Sec'y, HHS*, 76 Fed. Cl. 328, 338 (2007). In the motion for review, petitioner criticized the special master's active role in the case, arguing it was contrary to the "traditional role of a judge." Judge Wolski rejected petitioner's argument. *See also Boley v. Sec'y, HHS*, No. 05-420V, 2008 WL 4615034, at *2-5 (Fed. Cl. Spec. Mstr. Sept. 9, 2008) (discussing the legislative history of the Vaccine Act and Congress's intent in assigning an active role to the special master); *Jane Doe/03 v. Sec'y, HHS*, No. [redacted], 2007 WL 2350645, at *3 (Fed. Cl. Spec. Mstr. Aug. 14, 2007) (order noting "special masters are not merely passive recipients of information").

Vaccine Act's statute of limitations, it was not only appropriate, but required, that I address the question of timeliness.

2. Opportunity to Respond to my Show Cause Order.

Petitioner also asserts that "[i]n no instance did [I] request that evidence of equitable tolling be delivered." Pet. Response at 5. Petitioner is incorrect. On February 4, 2014, I informed the parties that the petition appeared to be untimely filed and allowed petitioner thirty days to file information which would establish the petition was timely filed or that equitable tolling was warranted. Show Cause Order at 4-5.

Moreover, at least six months earlier on at least two occasions, I informed petitioner that his claim appeared to be untimely filed and that we would need to address this issue. *See* Order, issued May 1, 2013, at 3; Order, issued Aug. 5, 2013, at 1. Also, respondent raised the issue of timeliness when responding to petitioner's former counsel's request to withdraw from the case and for interim attorneys' fees and costs. *See* First Response, filed Jan. 9, 2013, at 1 n.2; Second Response, filed Jan. 9, 2013, at 2-3. Thus, petitioner had ample notice that he would need to establish that his claim was timely filed.

On March 6, 2014, petitioner filed his response to my Show Cause Order. Rather than requesting additional time, petitioner presented multiple arguments that the petition was timely filed or equitable tolling and equitable estoppel should apply. Petitioner requested that I "continue the discovery phase" to allow him to gather additional evidence of vaccine causation, claiming that such evidence will support his equitable tolling and equitable estoppel arguments as "evidence of the existence of a causal link." Pet. Response at 6. Petitioner appears to conflate the issues of timely filing and vaccine causation in arguing the applicability of a discovery rule.

Because I am dismissing petitioner's claim as untimely filed, it is not necessary to reach the issue of whether V.K.'s condition was vaccine caused. As I indicated in Section II and will discuss further in Parts 3 and 4, a causal connection or knowledge thereof is not required to trigger the statute of limitations. The lack of knowledge of a causal connection is not grounds for equitable tolling. Thus, any additional information petitioner may gather regarding vaccine causation is not relevant to the question of whether the petition was timely filed. However, since petitioner alleges fraud and misconduct by the CDC and insists more evidence is required to support his argument for equitable tolling and equitable estoppel, I will address petitioner's request for additional discovery in more detail in Part 4 below.

3. Actual Notice and Causal Connection.

Petitioner claims he did not have notice of V.K.'s diagnosis until he received Dr. McCallon's report which was written "well after" the November 1, 2000 evaluation.[19] Pet. Response at 3. He asserts that the "[s]ymptoms of [a]utism are shared with any number of conditions [and] are undistinguishable until an expert diagnoses the collage of symptoms to determine an injury exists." *Id.* at 4. In essence, he argues not only that a diagnosis of autism is necessary to trigger the running of the statute of limitations, but that he must have had actual knowledge of the diagnosis.

However, it is "the first symptom or manifestation of an alleged vaccine injury, not the first date when diagnosis would be possible, that triggers the statute of limitations." *Carson*, 727 F.3d at 1369. In *Carson*, the Federal Circuit found that speech delay qualified as a first symptom of autism despite the possibility that it may not be sufficient for a diagnosis of autism, "may be indicative of a variety of conditions or ailments," and that a lay person may not "appreciate the medical significance" of the speech delay. *Id.* (quoting *Markovich v. Sec'y, HHS,* 477 F.3d 1353, 1357 (Fed. Cir. 2007)). Because there is evidence that V.K. exhibited speech delay and other symptoms of autism months before his diagnosis, it does not matter when petitioner received notice of V.K.'s diagnosis.

Petitioner also argues that the Vaccine Act's "statute of limitations cannot begin to run until there is some evidence of a causal connection." Pet. Response at 4. This argument raises anew the same argument unsuccessfully urged by petitioners in *Cloer I*[20] and the argument adopted by the panel decision in *Cloer II,*[21] which was rejected by the Federal Circuit sitting en banc in *Cloer III.*[22] In *Cloer*, the petitioner contended that the medical community at large had to recognize a causal connection between a vaccine and an injury in order to trigger the running of the statute of limitations. The en banc Circuit rejected this argument and held that the medical community had to recognize a symptom as one of the injury claimed. Effectively, the construction urged by petitioner would eliminate the statute of limitations for any injury that the medical community at large did not yet (or never did) recognize as one caused by a vaccine.

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[19] The report itself is not dated, indicating only that the evaluation occurred on November 1, 2000. *See* Pet. Ex. 5, p. 2.

[20] *Cloer v. Sec'y, HHS*, 85 Fed. Cl. 141, 149 (2008).

[21] *Cloer v. Sec'y, HHS*, 603 F.3d 1341, 1345-46 (Fed. Cir. 2010).

[22] *Cloer*, 654 F.3d at 1339-40.

Ignoring the Federal Circuit's clear holding in *Cloer III* that the Vaccine Act does not include a discovery rule,[23] petitioner claims that a discovery rule is applicable because the "Vaccine Compensation Act falls within the Federal Tort Claims Act" (FTCA) which allows a discovery rule. Pet. Response at 4.

Petitioner is incorrect. The FTCA allows "civil actions on claims against the United States . . . for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment." 28 U.S.C.A. § 1346(b)(1). The Vaccine Act does not "fall within" the FTCA. It is a separate no-fault tort reform program in which "wrongfulness" or negligence is irrelevant. Claims filed under the Vaccine Act are subject to its statute of limitations as set forth in § 16(a), not the FTCA's statute of limitations (28 U.S.C.A. § 2401(a)).

Petitioner urges me to ignore *Cloer* and find that a discovery rule is allowed under the Vaccine Act. I decline to do so.

4. Equitable Tolling and Equitable Estoppel.

Petitioner also argues that alleged misconduct by the CDC is a basis to apply equitable tolling and equitable estoppel in V.K.'s case. Pet. Response at 5. Assuming, arguendo, that the allegations of misconduct are true, such actions do not automatically result in the tolling of the statute of limitations. Petitioner has failed to show that the alleged actions of the CDC prevented him from filing his petition before the expiration of the statute of limitations.

a. Requirements for Equitable Tolling and Equitable Estoppel.

In *Cloer III*, the Federal Circuit held "equitable tolling under the Vaccine Act due to unawareness of a causal link between an injury and administration of a vaccine is unavailable." 654 F.3d at 1345. However, the Circuit specifically noted that the petitioner in *Cloer* did not argue that she was the victim of fraud or duress. *Id.* at 1344. Because the petitioner alleges misconduct by "employees of the Respondent" (Pet. Response at 5), and such conduct might, conceivably, warrant tolling or estoppel on equitable grounds, I examine what petitioner must demonstrate to warrant application of either equitable tolling or equitable estoppel.

"[T]he doctrine of estoppel is a judicial remedy by which a party may be precluded by his own act or omission, from asserting a right to which he otherwise would have been entitled." *Henry v. United States*, 14 Cl. Ct. 795, 799

[23] In *Cloer III*, the Federal Circuit held that the Vaccine Act does not include either an explicit or implied discovery rule. 654 F.3d at 1337 (en banc), *cert. denied, Cloer v. Sebelius*, 132 S.Ct. 1908 (2012). The Circuit's holding is unambiguous.

(1988), *aff'd*, 870 F.2d 634 (Fed. Cir. 1989). The party relying upon equitable estoppel must show that she reasonably relied to her detriment on the opposing party's misrepresentations. *Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51, 59 (1988) (citing Restatement (Second) of Torts § 894(1) (1979)); *see, e.g., Lyng v. Payne*, 476 U.S. 926, 935 (1986) (holding detrimental reliance was not shown).

In finding that equitable tolling applies to a federal statute of limitations, the Supreme Court cited cases involving equitable estoppel. *Irwin*, 498 U.S. at 96 n.4 (citing *Glus v. Brooklyn Eastern District Terminal*, 359 U.S. 231 (1959); *Holmberg v. Armbrecht*, 327 U.S. 392 (1946)).[24] Observing that federal courts have employed equitable relief sparingly, the Supreme Court indicated that the equitable tolling of federal statutes of limitations has been allowed "where the claimant has actively pursued his judicial remedies by filing a defective pleading during the statutory period **or where the complainant has been induced or tricked by his adversary's misconduct into allowing the filing deadline to pass**." *Irwin*, 498 U.S. at 96 (emphasis added). Petitioner here alleges misconduct on the part of respondent.

The basis for petitioner's claim is that, during an October 2003 visit to the CDC when he and two other people were provided access to the Vaccine Safety Datalink ["VSDL"],[25] they discovered data which showed an "increase of relative risk of autism . . . [that] is significant" for children who had received thimeroal-containing DTaP vaccines. Pet. Response at 2. When Mr. Krenik and his two colleagues returned in January 2004, they were denied access to the full records of these children and some information previously available was "blacked out," and that "one contractor testified at [an] August IOM[26] hearing that he was ordered to destroy data sets 'to protect privacy.'" Pet. Response at 3 (quoting a book by David Kirby, *Evidence of Harm*).

I need not determine if petitioner's allegations are true because, even if completely accurate, petitioner has not shown they prevented him from timely filing his petition.

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[24] As one of my colleagues observed, the Supreme Court appeared to include equitable estoppel, which sets aside the statute of limitations, as a subset of equitable tolling. *See Young v. Sec'y, HHS*, 1994 WL 879450, at *4-5 (Fed. Cl. Spec. Mstr. Aug. 26, 1994).

[25] The VSDL is a database that was "created in 1991 by the CDC to link medical events, vaccine history (by manufacturer and lot number), and demographic information from several health maintenance organizations, providing a method for monitoring vaccine safety issues." *Dwyer*, 2010 WL 892250, at *67 n.284 (citing T. Verstraeten, et al., *Safety of Thimerosal–Containing Vaccines: A Two–Phased Study of Computerized Health Maintenance Organization Databases,* PEDIATRICS 112(5): 1040 (2003), filed as exhibit 247 on the Petitioners' Master List in the Theory 2 OAP test cases).

[26] IOM stands for the Institutes of Medicine. *See King v. Sec'y, HHS*, No. 03-584V, 2011 WL 5926126, at 13 n.10 (Fed. Cl. Spec. Mstr. Sept. 22, 2011) (information regarding the IOM).

Since the Vaccine Act's statute of limitations is not triggered by the discovery of a causal connection between vaccine and injury, misconduct or misrepresentations in late 2003 or early 2004 cannot be the reason petitioner did not timely file V.K.'s claim. Based on petitioner's own statements about onset of V.K.'s autistic behaviors when V.K. was two years of age, the claim should have been filed by no later than June 2003. In arguing equitable estoppel, petitioner references events that allegedly occurred five to six months after the statute of limitations had expired. Thus, even if the alleged misconduct were sufficient to estop the government from asserting the statute of limitations bar to this petition, petitioner had already missed his filing deadline before the misconduct occurred. Petitioner filed his petition on December 1, 2003, at least one month before he claims he and his team were denied access and given only altered scientific data (January 2004).

If petitioner is alleging that the CDC or other government agencies concealed evidence of vaccine causation prior to the expiration of the statute of limitations (an argument he has not clearly made or provided evidence to support), other sources of information regarding a potential causal connection between thimerosal-containing vaccines and autism existed.

In 2001, the IOM released a report addressing the possibility of a link between thimerosal-containing vaccines and certain neurodevelopmental disorders such as autism. Although the IOM was unable to conclude if a causal relationship existed,[27] it supported calls for the removal of thimerosal from vaccines, noting that thimerosal had been removed from most vaccines given to infants, children, and pregnant women, and indicated further removal might be warranted. IOM 2001 Report at 8.

Moreover, in July 2002, when the OAP was formed, the order creating the "short form" petition reflected the expectation that claims of a causal connection between thimerosal-containing vaccines and autism would be included in the omnibus proceeding.[28] Additionally, at least one medical journal article was

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[27] The IOM found "that the evidence [was] inadequate to accept or reject a causal relationship." IOM, IMMUNIZATION SAFETY REVIEW: THIMEROSAL CONTAINING VACCINES AND NEURODEVELOPMENTAL DISORDERS (2001) ["IOM 2001 Report"] at 5. Although the IOM described the hypothesized association as "not established" and "rest[ing] on indirect and incomplete information," it categorized the hypothesis as biologically plausible. IOM 2001 Report at 4. In a later 2004 study addressing the question of a link between vaccines and autism, the IOM recognized the confusion created by the use of the term "biologically plausible," indicating that it now used a different system to describe the biological mechanism which might be involved. IOM, IMMUNIZATION SAFETY REVIEW: THIMEROSAL CONTAINING VACCINES AND NEURODEVELOPMENTAL DISORDERS (2004) ["IOM 2004 Report"] at 3. In that later report, the IOM concluded "the evidence favor[ed] rejection of a causal relationship between thimerosal-containing vaccines and autism. IOM 2004 Report at 7.

[28] Filing the "short form" petition authorized by the order asserted a claim that either the measles, mumps, and rubella vaccine or a thimerosal-containing vaccine, or both, caused autism spectrum disorders. *See* Autism General Order #1, filed July 3, 2002, Exhibit A, Master Autism Petition for

published in 2001, raising the hypothesis that autism was a novel form of mercury poisoning. *See, e.g.*, S. Bernard, et al., *Autism: a novel form of mercury poisoning* 56(4): 462-71 (2001), filed as exhibit 262 on Petitioners' Master List in the Theory 2 OAP test cases.

There is ample evidence that government agencies were actively and publically exploring a possible thimerosal-autism connection prior to the alleged fraudulent activities. The government had requested that the IOM study such a connection, leading to the 2001 IOM Report, as well as the IOM 2004 Report. incidentubthere is ample evidence that they are not. Through the OAP, and the unprecedented level of discovery afforded the litigants prior to the test case hearings, this court was examining the issue as well. I note that more than 2000 autism petitions had been filed by the time of the alleged misconduct, many alleging a thimerosal-autism connection. As petitioner noted, the CDC gave his team full access to VSDL information in October 2003. There is nothing to indicate the CDC would not have done so earlier if petitioner had asked.

In *Irwin*, the Federal Circuit explained that courts "have generally been much less forgiving in receiving late filings where the claimant failed to exercise due diligence in preserving his legal rights." 498 U.S. at 458 (citing *Baldwin County Welcome Center v. Brown*, 466 U.S. 147, 151 (1984)). Thus, courts have found that equitable tolling is not warranted when the needed information could have been obtained through due diligence from other sources. *See, e.g., A.Q.C. ex rel. Castillo v. United States*, 715 F.Supp.2d 452, 461-62 (S.D.N.Y. 2010) (holding that the FTCA statute of limitations should not be equitably tolled until plaintiff discovered her obstetrician was a federal employee, given that the information could have been obtained from numerous other sources).

As I noted in Part 3, the statutes of limitations in the Vaccine Act and in the FTCA differ but, even in medical malpractice claims under the FTCA, the accrual of the statute of limitations is postponed only until "the plaintiff has or **with reasonable diligence should have discovered** the critical facts of both his injury and its cause. *Barrett v. United States*, 689 F.2d 324, 327 (2d Cir. 1982) (emphasis added). In *Barrett,* the government controlled the information regarding the deceased's cause of death and did not just fail to come forward with evidence of misconduct, it actively concealed it by providing the family with a false cause of death.[29] *Id.* at 330. In this case, petitioner has failed to prove that he exercised due diligence in discovering a thimerosal-autism connection.

Even when the facts are viewed in the light most favorable to petitioner, he has not established that either equitable estoppel or equitable tolling applies to

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Vaccine Compensation at 2, which can be found on the court's website at http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf).

[29] The plaintiff in *Barrett* was the daughter of an individual who was killed while unknowingly serving as a test subject in chemical warfare experiments being conducted by the government. *Id.* at 326.

V.K.'s claim. Even taking his fraud allegations as true, he is unable to demonstrate that the governmental activity of which he complains impaired his ability to timely file V.K.'s claim.

b. Request for Additional Discovery.

Whether thimerosal-containing vaccines can or do cause autism spectrum disorders is not relevant in deciding whether this claim was timely filed. Nevertheless, I will briefly discuss the basis for petitioner's assertions that the purported thimerosal connection should be reexamined.

Petitioner claims that an unpublished study is evidence of a causal connection between the use of thimerosal-containing vaccines and the development of autism. Pet. Response at 1-2; *see* Pet. Ex. 19 (abstract of unpublished study titled *Vaccine Safety Datalink Analysis Confirms Link Between Neurodevelopment Disorders and Thimerosal-Containing Childhood Vaccines in the U.S.*). Although he does not identify the other two members of the team that produced the study, the abstract that petitioner filed indicates the study was authored by David A. Geier, B.A.; Vale Krenik, B.A.; and Mark R. Geier, M.D., Ph.D. Pet. Ex. 19 at 1. Both the type of study performed and petitioner's co-authors cast considerable doubt on the validity of petitioner's assertions that exploration of the autism-thimerosal connection is still warranted.

Petitioner's assertion that more discovery is necessary to demonstrate fraud is part of his effort to show that thimerosal causes autism and that a government cover-up tainted the OAP test cases. Petitioner has based his arguments regarding vaccine causation and request for additional discovery on an uncompleted study that cannot, by the nature of the study described, demonstrate a causal connection. Moreover, the study's authors have yet to produce any study on this topic considered as reliable evidence. I find that the additional discovery requested could not affect the timing problem in this claim, much less provide reliable evidence of a causal connection.

(1) Misplaced Reliance on an Ecological Study.

Petitioner describes an ecological study performed using data from the VSDL and claims it shows evidence of a "causal connection between the use of thimerosal-containing vaccines and the development of autism." Pet. Response at 2.

In *Dwyer*, the Theory 2 OAP test case, I discussed the strengths and weaknesses of several different types of epidemiological studies in demonstrating causality. *See Dwyer*, 2010 WL 892250, at *65-67. Petitioner's exhibit 19 describes an ecological study examining trend lines comprised of neurodevelopmental disorders and thimerosal-containing vaccines. Even if the trend lines are similar, such a study can only show that further study of the two

events may be warranted. *Dwyer*, 2010 WL 892250, at *66-67. "[A]n ecological study cannot determine if one event is caused by another," and "[i]nterpreting two similar trend lines in causal terms is called the 'ecological fallacy.'" *Dwyer*, 2010 WL 892250, at *66. In general, ecological studies are more susceptible to bias, cannot distinguish a small association from no association, and are afforded less weight than controlled studies. *Id.* An ecological study is helpful if it rules out a causal connection but "cannot serve as evidence of causation." *Id.* Thus, the "study," which petitioner did not file, would be useless as evidence of causation.

(2) Reliance on Research by the Geiers.

The study's co-authors, Mark and David Geier, are a father and son team who have authored numerous studies claiming a causal connection between vaccines and autism. Their studies connecting the MMR vaccine and autism and thimerosal-containing vaccines and autism were heavily criticized by the IOM in its 2004 study on vaccines and autism.[30] In evaluating an unpublished analysis authored by the Geiers, which could be the study abstract in Pet. Ex. 19, the IOM concluded the results were "uninterpretable and, as such, noncontributory with respect to causation." IOM 2004 Report at 52. In particular, the IOM noted the Geiers had not provided the basis for their calculations or a description of their methods and additional data.[31]

The Geier studies were also addressed in my *Dwyer* decision. I noted that the only studies which showed a connection between thimerosal-containing vaccines and autism were studies co-authored by the Geiers. *Dwyer*, 2010 WL 892250, at *71. Because petitioners' own expert in the OAP test cases commented that "the Geier studies were not reliable as evidence," I did not rely

[30] The Geiers authored six of the seven studies which reported an association between thimerosal and autism. *See* IOM 2004 Report at 51-52, 55-62, 65, 66-83 (Table 9) (discussing the thimerosal studies in detail). The seventh study (which was not authored by the Geiers) was an unpublished, uncontrolled study. *Id.* at 6-7. The IOM described the Geier studies as having "serious methodological flaws," their analytic methods as "nontransparent," and "their results uninterpretable, and therefore noncontributory with respect to causality." *Id.* at 7. The Geiers submitted the only two studies which reported an association between the MMR vaccine and autism, and the IOM similarly criticized those studies. *Id.* at 7; *see id.* at 83, 86-111 (Table 10), 119-20, 122-23, 126 (discussing the MMR studies in detail).

[31] In 1993, the Supreme Court concluded the general acceptance test in *Frye v. United States,* 293 F. 1013, 1014 (D.C. Cir. 1923) was superseded by the Federal Rules of Evidence and held that the Rules required admitted scientific testimony or evidence to be relevant and reliable. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 589 (1993); *see also Terran v. Sec'y, HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (indicating it is appropriate for special masters to use the *Daubert* factors when assessing the reliability of vaccine causation theories). While cautioning that the question of scientific validity should focus on principles and methodology rather than the conclusions reached (*Daubert*, 509 U.S. at 594-95), the Supreme Court indicated that one factor to consider is whether a technique or theory can or has been tested (*id.* at 593). The Geiers' consistent failure to provide the data and methodology used in studies which they claim show vaccine causation greatly undercuts the scientific validity of these studies.

upon them or discuss them further. *Id.* The only exception was the Young study[32] which was introduced after petitioners' epidemiology expert finished testifying and was excused. *Dwyer*, 2010 WL 892250, at *71 & n.301. Respondent's experts in epidemiology were highly critical of the Young study.[33] Based on their criticisms, I afforded the study "little weight." *Dwyer*, 2010 WL 892250, at *72.

The special masters who heard the other two test cases came to a similar conclusion regarding the reliability of the Geier studies. *See King,* 2010 WL 892296, at *68 (finding all the Geier epidemiological studies to be unreliable); *Mead*, 2010 WL 892250, at *39 n.78 (criticizing the Geier studies while noting "a number of courts have expressed concerns about the reliability of their work").

The special master handling the costs incurred by the PSC to address the general causation issues involved in Theory 2 refused to pay for the Young study, finding that it "did not add any value to the petitioners' causation presentation in [the] case." *King*, 2011 WL 5926126, at *9 (emphasis removed). The special master discussed criticisms of the study, evaluations of prior articles by the Geiers, and the general credibility of Dr. Geier[34] as an expert witness. *King*, 2011 WL 5926126, at *9-17. The special master included an extensive list of vaccine and non-vaccine decisions in which judges and special masters not only questioned Dr. Geier's honesty but noted his tendency to offer testimony in areas which are outside his medical expertise. *King*, 2011 WL 5926126, at *10-13. The special master observed that Dr. Geier had little to no expertise in epidemiology.[35] *King*, 2011 WL 5926126, at *15-16.

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[32] The Young study was authored by the Geiers and Dr. Heather Young. Like the one referenced by petitioner, it is an ecological study using information from the VSDL. This study appears to have been published in the Journal of the Neurological Sciences on May 1, 2008. *See King*, 2011 WL 892296, at *68 n.101 (indicating the following article citation: Heather A.Young, David A. Geier, Mark R. Geier, *Thimerosal Exposure in Infants and Neurodevelopmental Disorders: An Assessment of Computerized Medical Records in the Vaccine Safety Datalink,* 15 J. NEUROLOGICAL SCI. 110 (2008)).

[33] Respondent's experts argued that this study was flawed for a variety of reasons such as the lack of data which would allow for verification of any calculations, a "mid-stream" change in the study's design, poor design for Table 3, and the inclusion of a broad range of differing disorders. *Dwyer*, 2010 WL 892250, at *71-72. One expert (Dr. Frombonne) noted that the birth cohorts did not use the same number, with one "outlier" group containing just 2,000 instead of the 40,000 children in most groups, and that invented numbers were added to the 1995 and 1996 data. *Dwyer*, 2010 WL 892250, at *71. In a subsequent letter, Dr. Young admitted that the study lost statistical significance if either the outlier group or invented numbers were removed, but defended the use of both. *Dwyer*, 2010 WL 892250, at *72.

[34] I note that Dr. Mark Geier's medical license was suspended in March 2012. *See Bast v. Sec'y, HHS*, No. 01-565V, 2012 WL 6858040, at *1 n.5 (Fed. Cl. Spec. Mstr. Dec. 20, 2012).

[35] As noted by the Supreme Court in *Daubert*, the wide latitude afforded to an expert "is premised on an assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline." 509 U.S. at 592. This assumption does not apply when an expert is opining outside of his discipline.

With reference to Dr. Geier as an expert witness, special masters have observed that his credibility has been so compromised that he should not be employed as an expert in Vaccine Act cases. *See, e.g., Masias v. Sec'y, HHS*, No. 99-697V, 2009 WL 1838979, at *39 (Fed. Cl. Spec. Mstr. June 12, 2009). More recently, the Geiers' activities have led to the loss of Dr. Geier's medical license in March 2012 (*see supra* note 34) and David Geier's fine by the State of Maryland for practicing medicine without a license (*see Arango v. Sec'y, HHS*, No. 09-318V, 2012 WL 4018028, at *9 n.20 (Fed. Cl. Spec. Mstr. Aug. 23, 2012)). *See also* Res. Reply at 2 n.2.

5. Former Counsel's Beliefs.

In his last argument regarding why his claim should not be dismissed, petitioner requests that I strike the admission of his former counsel regarding the merits of his causation case. Pet. Response at 5.

When seeking to withdraw as attorney of record, petitioner's former counsel indicated that he did not believe there was, in light of the decisions in the OAP test cases rejecting the theories advanced, a reasonable basis to proceed with petitioner's claim (Motion, filed Dec. 21, 2012, at 5). Former counsel added that petitioner disagreed with his belief (Reply, filed Feb. 6, 2013, at 3). When granting counsel's motion to withdraw, I found that the personal belief of petitioner's former counsel prevented him from adequately representing petitioner's interests. However, I expressed no opinion as to the validity of counsel's beliefs and have given no weight to his opinion in deciding that this case was untimely filed. Because the opinion of former counsel has no effect on my decision, I decline to grant petitioner's request.

IV. Conclusion.

Petitioner has the burden to show timely filing. Petitioner has failed to do so. There is preponderant evidence that this case was not 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. § 16(a)(2). Furthermore, petitioner has not demonstrated that either equitable tolling or equitable estoppel preclude application of the statute of limitations in this case.

This claim is dismissed as untimely filed. The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

Denise K. Vowell
Chief Special Master