

In the United States Court of Federal
Claims

OFFICE OF SPECIAL MASTERS

No. 03-0632V

Originally filed September 28, 2015

Refiled in redacted form May 23, 2016

For Publication

R.K, on behalf of A.K., a minor,

Petitioners,

v.

SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

Respondent.

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Autism; OAP;
Compelling Expert Evidence;
Judicial Estoppel;
Filings After Closure of Record;
Newly Discovered Evidence

John F. McHugh, New York, N.Y. for petitioners.

Heather L. Pearlman, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON MOTIONS¹

Vowell, Special Master:

This ruling resolves all outstanding motions. It also provides a written rationale for rulings issued summarily as this case proceeded to and through a causation hearing. In summary, I deny: (1) a motion to compel a non-treating physician to testify or produce documents; (2) a motion to apply judicial estoppel with regard to causation; (3) the admission of an expert report from another Vaccine Act case; and (4) a motion to strike the testimony of one of respondent's witnesses. I also address two motions that are now moot. I grant the motion to admit a number of medical journal articles filed long after the evidentiary record closed, but only because they are largely cumulative and engaging in the analysis necessary to exclude them would unnecessarily prolong the resolution of this case.

¹ [* * * This Ruling was originally issued on September 28, 2015. In this public Ruling, the family name of the petitioners has been redacted pursuant to their request. In addition certain matter improperly filed by the petitioners has also been redacted, upon the instructions of Special Master Vowell, from pp. 26, 27, and 32. See Order filed on Dec. 2, 2015.]

I. Procedural History.

The convoluted procedural history of this case is set forth in some detail, as it places the resolution of the outstanding motions in context. It will be incorporated by reference in the causation decision that follows my ruling on these issues.

A. The Initial Petition.

On March 24, 2003, petitioners [* * * * *] filed a “Short-Form Petition for Vaccine Compensation” under the National Childhood Vaccine Injury Act² [“Vaccine Act”] on behalf of their son, A.K. Such petitions, authorized by Autism General Order #1,³ alleged in a summarized fashion that the vaccinee has a disorder on the autism spectrum. By filing a short form petition, they opted into the Omnibus Autism Proceeding [“OAP”], and their case was stayed while discovery regarding general causation issues was conducted.⁴

B. The OAP.

Beginning in 1997, but peaking numerically in 2002-03, thousands of petitions were filed alleging either that the measles, mumps, and rubella [“MMR”] vaccine or thimerosal, an ethyl mercury preservative used in multi-dose vials of many vaccines, caused ASD. The sheer volume of petitions filed—more than 1,300 new petitions in 2002 alone—led to the creation of the OAP.⁵ Omnibus programs had been used

² The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 *et seq.* (2012). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Vaccine Act.

³ By electing to file a Short-Form Autism Petition for Vaccine Compensation, petitioners alleged that:

As a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the vaccinee 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.

Autism General Order #1, 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002), Exhibit A, Master Autism Petition for Vaccine Compensation at 2 (found at 2002 WL 31696785, 2002 U.S. Claims LEXIS 365, or <http://www.uscfc.uscourts.gov/sites/default/files/autism/Autism+General+Order1.pdf>) (last visited on July 27, 2015). In filing a short-form petition, petitioner joined the Omnibus Autism Program [“OAP”], explained in more detail, *infra*.

⁴ See Autism General Order #1, 2002 WL 31696785, at *5-7 (indicating claims filed using the short form petition will be included in the OAP and automatically stayed while litigation on general causation issues is conducted); see *also* Notice, issued Apr. 9, 2003, at 1 (describing the OAP as “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.”).

⁵ See Autism General Order #1. It is impossible to determine precisely how many petitions alleging vaccine causation of autism were filed in the OAP, as the nature of suit codes used to track Vaccine Act cases do not contain a code for autism or similar neurodevelopmental disorders. Estimates range from

previously in Vaccine Act cases to make causation determinations in groups of cases alleging that a particular vaccine caused a specific injury, but the OAP was, by far, the largest grouping of similar cases.⁶

Following a series of meetings with an informal advisory committee (comprised of petitioners' counsel representing many of the Program claimants and legal and medical representatives of the Secretary of Health and Human Services), the Office of Special Masters ["OSM"] adopted a plan that would allow a period of discovery, followed by the selection and litigation of test cases on the theories of causation presented. Autism General Order #1 at 2-3. The conclusions reached on general causation and the evidence adduced in the test cases would then be used to resolve the remaining claims. *Id.* at 3. Those who had already filed petitions were allowed to "opt in" or "opt out" of the proceedings, and future claimants could automatically "opt in" by filing the short form petition included as Attachment B to Autism General Order #1. *Id.* at *6-8.

Attorneys representing petitioners created the Petitioners' Steering Committee ["PSC"] to coordinate the OAP litigation. The PSC acknowledged that there was insufficient evidence at the time the OAP was created to prove vaccine causation, but averred that such evidence could be found through discovery and ongoing scientific investigations. Petitioners sought and received an extended period of delay to conduct discovery and prepare to litigate the test cases.

Nearly five years after the OAP was created, litigation in the test cases began, with the PSC presenting two different theories on the causation of ASD in two sets of test cases. The first alleged that thimerosal-containing vaccines and the MMR vaccine, in combination, could cause ASD (Theory 1). The second alleged that thimerosal-containing vaccines could cause ASD (Theory 2). In accordance with the intent that OAP test case evidence be made available to assist with the resolution of the remaining OAP cases, the evidence (including expert reports, transcripts of testimony, trial presentation materials and trial exhibits, and lists of the medical journals and other documents filed by the parties) was posted on the Court of Federal Claims website.⁷

Decisions in each of the three Theory 1 test cases, which were tried in 2007, rejected petitioners' causation theories. *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

5,400 to over 6,000 cases, with the latter number including cases filed after the initial test case hearing dates were announced.

⁶ See *Hennessey v. Sec'y, HHS*, No. 01-190V, 2009 WL 1709053 (Fed. Cl. Spec. Mstr. May 29, 2009), *aff'd*, 91 Fed. Cl. 126 (2010) (discussing the different types of omnibus proceedings conducted in the Vaccine Program).

⁷ See <http://www.uscfc.uscourts.gov/docket-omnibus-autism-proceeding> (last visited on September 17, 2015). The parties in the test cases all filed explicit written consent to make these materials publicly available. See, e.g., *Mead v. Sec'y, HHS*, No. 03-215V, 2010 WL 892248, at *1 n.1 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (referencing petitioners' and respondent's written consent in that case).

(Fed. Cir. 2010); *Snyder v. Sec'y, HHS*, No. 01-162, 2009 WL 332044, *aff'd*, 88 Fed. Cl. 706 (2009).⁸

Decisions in the three Theory 2 test cases, which were tried in 2008, also rejected the causation theory presented. Petitioners did not seek review of the special masters' decisions. *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*, 2010 WL 892248.

An impressive body of medical and scientific evidence was adduced in the OAP test cases, with the three special masters who heard this evidence finding that the issue of vaccine causation was not a close call. See *e.g.*, *King*, 2010 WL 892296, at *90; *Snyder*, 2009 WL 332044, at *198. Each of the three special masters independently determined that the medical theories advanced were not reliable and that the test case petitioners had failed to produce preponderant evidence of causation. The OAP test case litigation concluded in 2010, with the last Federal Circuit decision affirming the dismissal of the final Theory 1 test case.⁹

C. Test Case for Theory 2 Litigation.

This case was reassigned to me on December 18, 2007, when the autism docket, handled from the beginning of the OAP by Special Master Hastings, was divided among three special masters in anticipation of the test case hearings. In early 2008, the PSC identified A.K.'s case as one of the three Theory 2 test cases. See Autism Update, issued in the OAP docket on Jan. 17, 2008, at 2-3.¹⁰ Mr. Thomas Powers, a member of the executive committee of the PSC, substituted as attorney of record, vice Steven Tannenbaum. See PSC Roster, filed in the OAP docket on Mar. 9, 2007; Motion to Substitute Attorney, filed Jan. 8, 2008 (granted the same day).

Over the next three months, the PSC filed expert reports addressing general causation under Theory 2 in the OAP docket and in the evidentiary record of this case.¹¹ The expert report of Dr. Elizabeth Mumper was submitted in support of both general

⁸ Petitioners did not appeal the Court of Federal Claims decision in *Snyder* to the Federal Circuit.

⁹ *Cedillo v. Sec'y, HHS*, 617 F.3d 1328 (Fed. Cir. 2010).

¹⁰ Throughout this ruling, I occasionally reference documents issued or filed in the OAP docket. Such documents will be specifically identified as a part of the OAP docket. Absent such identification, all other references are to documents appearing on the docket of this case.

¹¹ Expert reports were filed in the OAP docket in late 2007 and early 2008 from Drs. Sander Greenland, Richard Deth, and Vasken Aposhian. These same reports were filed in the evidentiary record in this case in early 2008. See Petitioners' Exhibits ["Pet. Exs."] 22-24. Although these reports are part of the evidentiary record in this case, only Dr. Deth's has clear relevance to the causation theory ultimately presented in this case. In essence, Dr. Deth's opinion in the Theory 2 test cases was much the same as his theory here. Many of the slides he used to illustrate his testimony in this case were virtually identical to the slides he used to illustrate his test case testimony.

causation and causation in A.K.'s case.¹²

Respondent also filed expert reports and curriculum vitae ["CVs"] from multiple experts, some addressing ASD in general and others addressing general causation with respect to Theory 2 in the evidentiary record of this case. See Respondent's Exhibits ["Res. Exs."] G-KK (CVs and expert reports from 15 experts).¹³ Additionally, she filed medical literature specifically focused on causation in this case. See Res. Exs. A-F.¹⁴

During this same time period, petitioners also filed medical and educational records. See, e.g., Pet. Exs. 2-21, 25-30.

D. Petitioners' Motion to Withdraw as a Test Case and from the OAP.

On April 10, 2008, approximately a month before Theory 2 test case hearings were scheduled to begin on May 12, 2008, petitioners filed a motion to withdraw A.K.'s case as a test case. Petitioners explained that they were not abandoning the theory "that thimerosal-containing vaccines (TCVs) were a substantial contributing cause of [A.K.'s] autistic symptoms" but wanted the opportunity "to develop and present evidence of additional and alternative causative factors." Motion, filed Apr. 10, 2008, at ¶ 1 (ECF No. 40).¹⁵ Petitioners also asked to withdraw from the OAP "in order to proceed to an individual hearing on compensation." *Id.* at ¶ 2. Respondent did not object and, as Autism General Order #1 indicated that any petitioner could ask to have his or her case heard individually at any time, I granted petitioners' motion. See Order, filed Apr. 15, 2008 (ECF No. 41); see also Autism General Order #1 at 8.

¹² Doctor Mumper's expert report was filed in the evidentiary record of this case on January 22, 2008. See Pet. Ex. 1. Although Dr. Mumper's expert report was filed in the OAP docket on January 8, 2008, it was subsequently withdrawn. At the digitally recorded status conference on Apr. 9, 2013, petitioners indicated that they did not intend to rely on Dr. Mumper's report and requested that I strike it. I orally granted their request. See audio recording at 2:42-44.

¹³ Although respondent later consented to the disclosure of the majority of these expert reports on the court's website (see Respondent's Consent, filed in the OAP docket on Feb. 2, 2009), the expert reports specific to this case were never filed in the OAP docket.

¹⁴ The medical literature filed during the period when this was one of the OAP test cases was not filed directly into the OAP docket, but it was included on the parties' "Master Lists." These lists were created in the Theory 2 test cases to avoid a problem that surfaced in the Theory 1 test cases. In the Theory 1 cases, multiple copies of the same medical journal article were filed and witnesses and counsel referred to the same documents by different exhibit numbers, causing confusion. In the Theory 2 test cases, the master lists were intended to comprise all of the medical literature filed by petitioners (Petitioners' Master List ["PML"]) and respondent (Respondent's Master List ["RML"]). As new expert reports were filed that referenced medical or scientific literature, that literature was added to and assigned exhibit numbers on the master lists. See Order, issued Dec. 12, 2007 in the OAP docket, at 1. If an article appeared on petitioner's list, respondent was not required to include that article on her list, and vice versa. *Id.* at 1 n.1. Respondent's Exs. A-F in this case appeared as RML 32, 111, 325, 509 and PML 46, 93 on the OAP docket's master lists. The RML journal articles were filed into the record of this case via a CD containing them. ECF No. 23.

¹⁵ Because there are more than 300 docket entries in this case, some of which were filed on the same dates, I will use the ECF docket number in most citations to identify the specific filing involved.

When requesting that their case be withdrawn as a Theory 2 test case, petitioners also requested that any case-specific material be withdrawn from the publically-available OAP docket. Motion, filed Apr. 10, 2008, ¶ 3 (ECF No. 40). Thus, Dr. Mumper's expert report was withdrawn from the OAP docket, but remained in the evidentiary record in this case until petitioners' request to withdraw it prior to the hearing. See January 8, 2008 Entry on OAP Docket (indicating it was no longer appropriate to post the expert report containing case-specific information on the court's website after the case was withdrawn as a test case).

Several months later (and after the test case hearings concluded), respondent asked to withdraw the CVs and expert reports of two of her experts because she determined their testimony would not be needed in the OAP Theory 2 cases.¹⁶ Respondent also requested that I remove them from the docket of this case. I granted respondent's request. See Order, issued July 29, 2008 (ECF No. 48). The CVs and expert reports for the other thirteen experts remained in the evidentiary record for this case.

In a later-filed exhibit list, petitioners failed to include any of their OAP expert reports. See Exhibit List, filed Apr. 13, 2013, at 1-2 (ECF No. 234) (listing Dr. Mumper's report as withdrawn and indicating "Not used for filing" for the exhibit numbers (22-24) used to designate the other OAP expert reports). The only OAP report that they had requested to strike was that of Dr. Mumper, and I had granted that request at the digitally recorded status conference held on April 9, 2013 (see 2:43). The only other expert reports withdrawn from the evidentiary record in this case with leave of court were the two reports and CVs withdrawn by respondent in July 2008. Thus, the expert reports for Drs. Deth, Greenland, and Aposhian remain part of the record of this case.

E. Proceeding as an Individual Case.

1. Proceeding Without Retained Counsel.

On May 22, 2008, [A.K.'s father] was substituted for Mr. Powers as the attorney of record for his son.¹⁷ [A.K.'s father] represented that he entered an

¹⁶ Respondent sought to withdraw the CV and expert report of Dr. Thomas Clarkson (Res. Exs. L, Z) and of Dr. Laszlo Magos (Res. Exs. K, Y). See Motion, filed July 8, 2008. Respondent withdrew these expert reports from the OAP proceedings in order to obviate the need for an additional hearing session in the Theory 2 test cases, as petitioners had requested the opportunity to question both experts in person and they did not appear as witnesses at the test case hearing. See Order, issued in the OAP docket on July 3, 2008, at 2.

¹⁷ [A.K.'s father] is an attorney who has represented more than 100 Vaccine Act petitioners on claims that vaccines caused autism spectrum disorders, as well as petitioners in other types of vaccine injury claims. A.K.'s case was originally filed by Steven Tannenbaum, who was replaced by PSC Executive Committee member Thomas Powers. After petitioners withdrew as a test case, Mr. Powers withdrew from representation. For about 19 months, [A.K.'s father] represented himself, his wife, and his son, before Mr. John McHugh entered an appearance. Although [A.K.'s father] was represented by Mr. John McHugh and Ms. Helen Sturm at the causation hearing, [A.K.'s father] remained actively involved in the presentation of his son's case (see, e.g., Transcript ["Tr."] at 139, 261-62, 1386, 1389, 1492, 1495, 1515) and occasionally attempted to interpose objections (see, e.g., Tr. at 326).

appearance to facilitate communication with the court, but that he was actively seeking another attorney to pursue A.K.'s claim. See Status Report, filed July 1, 2008 (ECF No. 45). Although respondent's counsel later objected to [A.K.'s father's] appearance, arguing that the case should be designated as *pro se*, I allowed [A.K.'s father] to remain attorney of record while he searched for representation. Order, issued Nov. 7, 2008, at 1 (ECF No. 50).¹⁸

For about 19 months, [A.K.'s father] attempted to find new counsel to represent A.K. He filed numerous status reports requesting enlargements of time and updating me on his progress (or lack thereof). See, e.g., Status Report, filed Aug. 4, 2009 (ECF No. 61). He filed medical records as they were created or became available. See Pet. Exs. 31-33 (ECF Nos. 51-52, 65). Other than the filing of medical records, petitioners did little to advance their claim during the period in which [A.K.'s father] was attorney of record.

I continued to press [A.K.'s father] to move his son's case toward resolution during this period, noting that when he withdrew from the OAP and indicated a desire to proceed as an individual case, he was no longer able to claim the benefit of being in the OAP "holding pattern" to avoid his obligation to prosecute his son's claim. Perhaps in frustration with my insistence that petitioners either needed to find substitute counsel or otherwise prosecute A.K.'s case themselves, [A.K.'s father] voiced a desire to return the case to the OAP during a status conference on November 3, 2008. I directed petitioners "to file a written motion requesting their case be redesignated as an OAP case as soon as possible." See Order, issued Nov. 7, 2008, at 1 (ECF No. 50). Petitioners never filed that motion.

2. Securing Representation.

On January 5, 2010,¹⁹ John F. McHugh filed a motion to be substituted as counsel in this case, and I granted the motion on January 7, 2010. However, the glacial pace of progress toward a causation hearing continued for many months thereafter. Mr. McHugh's representation has been marked with missed deadlines, repeated requests for delays, late filings, and difficulties in properly designating and filing exhibits. His failure to meet deadlines nearly cost petitioners the opportunity to fully litigate their son's claim.

In the first two months Mr. McHugh represented petitioners, he missed both deadlines set for status reports informing me that he had met with petitioners and was ready to discuss the way ahead in this case.²⁰

¹⁸ The practical reason to allow [A.K.'s father] to enter an appearance as attorney of record was to continue to allow documents to be filed electronically. [A.K.'s father] was (and is) an attorney admitted to the bar of the Court of Federal Claims. I did caution him, however, that it was unlikely he could be paid attorney fees for his work on his son's case.

¹⁹ Mr. McHugh filed a defective motion to substitute as counsel on December 2, 2009 (ECF No. 73).

²⁰ I had an initial status conference with Mr. McHugh more than two weeks after his notice of appearance was properly filed. See Order, issued Jan. 20, 2010, at 1 (ECF No. 76). He informed me he had not yet

Between January and August 2010, petitioners' counsel ²¹ did very little to advance the case. Although he reported in March 2010 that he had retained an expert²² who was reviewing the case and expected the expert to produce a report in about two to two and one half months (Status Report, filed Mar. 5, 2010 (ECF No. 78)), Dr. Kinsbourne's very cursory report was not filed until October 26, 2010 (ECF No. 100).

At the next status conference, held about 90 days later to allow Dr. Kinsbourne time to prepare his expert report, petitioners indicated that they intended to file an application for interim costs due to the significant fees involved in retaining medical experts. See Order, issued June 8, 2010, at 1 (ECF No. 79). It became apparent during the conference that petitioners had not filed all medical records in their possession. See *id.* Thus, I ordered petitioners to file all remaining medical records by June 18, 2010; any application for interim fees and costs by July 23, 2010; and a status report informing me of their progress in obtaining expert reports by August 9, 2010. See *id.*

Petitioners filed medical records and a notice of compliance (ECF Nos. 93, 95) on June 16 and 17, 2010²³ and an out of time²⁴ status report (ECF No. 96) on August 13, 2010. In their status report, petitioners informed me that (1) Dr. Kinsbourne was unable to complete his expert report as he was awaiting further diagnostic tests; (2) Dr. Kinsbourne could not specify when his expert report would be completed; and (3) petitioners were pursuing another unnamed expert. Status Report, filed Aug. 13, 2010, at 1-2 (ECF No. 96). Petitioners suggested that they file monthly status reports until

met with petitioners or familiarized himself with the case and estimated that he needed an additional thirty days to do so. See *id.* I scheduled another status conference for February 19, 2010 and ordered petitioners to file a status report informing me that they had met with counsel and discussed their case by February 12, 2010. *Id.* Petitioners missed this deadline. On February 18, 2010, I cancelled the status conference scheduled for February 19, 2010, ordered Mr. McHugh to obtain A.K.'s medical records and familiarize himself with the case as soon as possible, and ordered petitioners to file a status report indicating that Mr. McHugh was ready to proceed by March 4, 2010. See Order, issued Feb. 18, 2010 (ECF No. 77). Petitioners missed the deadline, but filed a late status report indicating that Mr. McHugh was reviewing A.K.'s medical records and that Dr. Marcel Kinsbourne had been retained as an expert and was reviewing the medical records as well.

²¹ All future references to petitioners' counsel in this ruling are to Mr. McHugh, petitioners' attorney of record. Ms. Helen Sturm, an attorney associated with Mr. McHugh, also appeared on behalf of petitioners at the hearings.

²² Doctor Kinsbourne was an expert for petitioners in both the Theory 1 and 2 test cases and, as I noted in *Snyder*, 2009 WL 332044, at *12, was something of a professional witness in Vaccine Act cases. He was thus well acquainted with the medical literature pertaining to both vaccines and autism.

²³ Petitioners attempted to file medical records on June 14, 2010 (ECF Nos. 84-91). However, the records were struck as they were not properly filed and used an incorrect event code ("15 week stipulation status report.") On June 16, 2010, petitioners properly filed Pet. Exs. 34-36. Identical records were filed again on June 17, 2010 (ECF Nos. 93, 95).

²⁴ Petitioners' status report was due on August 9, 2010. Petitioners were reminded of the process used to request additional time under Vaccine Rule 19(b) and warned that future out of time filings would be struck. See Order, filed Aug. 18, 2010, at 1, n.1.

their expert reports were filed. *Id.* at 2.

I rejected this suggestion²⁵ and, instead, ordered petitioners (1) to identify their potential expert and outline the steps taken to contact the expert, (2) to file a status report informing me when Dr. Kinsbourne had received the medical records he needed and when his report could be filed, and (3) to inform me if Dr. Kinsbourne could not complete his expert report in seventy-five days and, if so, to file a letter from Dr. Kinsbourne explaining why and providing a date when his report would be completed. Order, filed Aug. 18, 2010, at 1-2 (ECF No. 97). Petitioners failed to meet any of these deadlines.

F. Dismissal of Petitioners' Claim.

During the period in which [A.K.'s father] was attorney of record and while Mr. McHugh was attempting to familiarize himself with this case, the OAP test case decisions were issued. Thereafter, many litigants, particularly those who had proceeded on the thimerosal theory (Theory 2), dismissed their claims. The PSC had not sought review of the Theory 2 test case decisions by the special masters, thus effectively concluding the OAP litigation of this theory. Many attorneys who were representing the test case litigants were seeking to withdraw from representation, based on their assessment that the causation theories they had pursued were no longer viable.

Against this backdrop, petitioners' apparent inability to find a doctor other than Dr. Kinsbourne willing to opine or to obtain a report on causation from Dr. Kinsbourne, coupled with the repeated missed deadlines, signaled to me that they had problems with their case. Accordingly, after petitioners missed the deadlines set forth in my August 18, 2010 order, I ordered them to show cause why their case should not be dismissed for failure to prosecute and comply with court orders. See Order to Show Cause, issued Sept. 3, 2010 (ECF No. 98). After petitioners ignored the deadline in the show cause order, I dismissed their petition on October 13, 2010.

G. Motion for Reconsideration.

Petitioners filed a motion on October 26, 2010, asking me to reconsider my decision dismissing their claim for insufficient proof and failure to prosecute.²⁶ After allowing the parties to present their arguments,²⁷ I granted petitioners' motion for

²⁵ I viewed petitioners' request to file monthly status reports as an effort to obtain more delays in the litigation of their causation claim. More than two years after petitioners had withdrawn as an OAP test case and indicated that they intended to proceed independently on their case, they had still not filed any report (other than Dr. Mumper's) that reflected a causation theory implicating vaccines as causal.

²⁶ With their motion for reconsideration, petitioners also filed additional evidence, declarations from [A.K.'s father, A.K.'s mother], and treating physician Dr. Marvin Boris as well as some medical literature and the long-delayed report from Dr. Kinsbourne. See Pet. Exs. 37-56.

²⁷ See Respondent's Response, filed Nov. 3, 2010 (ECF No.102); Petitioners' Reply, filed Nov. 6, 2010 (ECF No. 104).

reconsideration. See Order, issued Nov. 12, 2010, at 2 (ECF No. 106).²⁸ I subsequently redacted, at petitioners' request, portions of the order granting the motion for reconsideration and withdrawing my dismissal decision.

H. Request for Pre-Payment of Interim Costs.

Following my withdrawal of the October 13, 2010 decision dismissing petitioners' claim, I ordered petitioners to file a status report informing me of the date by which they expected to file the report of their new expert, Dr. Richard Frye, and an "amended petition clarifying their theory of causation." Scheduling Order, issued Nov. 15, 2010, at 1 (ECF No. 107). In response, petitioners filed a motion seeking additional time to file their amended petition, pre-approval of Dr. Frye as an expert, and interim costs in the amount of \$5,000²⁹ to be paid as a retainer to Dr. Frye. Motion, filed Nov. 30, 2010, at 6 (ECF No. 109). On January 28, 2011, I granted the motion for additional time to file an amended petition and awarded interim costs in the amount of \$5,000.³⁰ Decision, issued Jan. 28, 2011. This decision was later withdrawn as moot, at 10 (ECF No. 121); see also Order, issued Feb. 28, 2011 (ECF No. 128) (ordering the decision withdrawn) because Dr. Frye could no longer opine or testify, based on changed employment.

I. Petitioners' First Amended Petition.

Petitioners filed their first amended petition on February 28, 2011. First Amended Petition (ECF No. 126).

A few weeks later, petitioners indicated they had retained Yuval Shafir, M.D. and requested an additional sixty days to file his report.³¹ Status Report, filed Mar. 9, 2011 (ECF No. 129). After petitioners filed Dr. Shafir's expert report,³² I ordered respondent to file an expert report, supplemental Rule 4 report, and any evidence from the OAP upon which she intended to rely. See Order, issued July 12, 2011. Respondent filed

²⁸ Because I granted petitioners' motion and ordered my decision to be withdrawn, I denied as moot petitioners' motion (ECF No. 101) to redact portions of the October 13, 2010 decision.

²⁹ This amount was based on an hourly rate of \$500 and, thus, constituted prepayment for ten hours of work.

³⁰ I also ordered petitioners to file "a bill documenting the charge and payment of Dr. Frye's retainer" by no later than February 28, 2012 and a more detailed bill within sixty days of the filing of Dr. Frye's expert report. On February 7, 2011, respondent filed a motion for reconsideration which I denied. See Order, filed Feb. 23, 2011, at 5 (ECF No. 124). However, I withdrew my decision awarding interim costs on February 28, 2011 after petitioners informed me that Dr. Frye was no longer opining in this case. See Order, filed Feb. 28, 2011 (ECF No. 128).

³¹ Petitioners' counsel reiterated this request in a status conference I held that day. Respondent did not object to the request. See Order, issued Mar. 9, 2011 (ECF No. 130). I granted the delay requested.

³² Petitioners filed Dr. Shafir's expert report and references on July 7, 2011. Pet. Ex. 63, Tabs 1-22 (ECF NO. Nos. 135-141). Because they had failed to file Dr. Shafir's expert report as a separate attachment, they re-filed the report and first four references on July 8, 2011. See Pet. Ex. 63, Tabs 1-4 (ECF No. 142).

her Rule 4 report and OAP evidence as ordered on October 10, 2011³³ but requested additional time to file her expert reports. See Motion, filed Aug. 5, 2011 (ECF No. 144). I granted respondent's request, allowing her until November 14, 2011 to file her reports. Order, issued Aug. 5, 2011.

Prior to respondent's deadline, petitioners informed me that they had retained another expert, Fran. D. Kendall, M.D. and expected to file her report in approximately two months. See Status Report, filed Oct. 20, 2011, at 1-2 (ECF No. 147).

In November 2011, respondent filed expert reports from Gerald Raymond, M.D., Judith Miller, Ph.D., and Christine McCusker, M.D. Respondent also indicated she would be filing a report from a mitochondrial disorder expert after Dr. Kendall's report was filed.³⁴ In December 2011, petitioners filed Dr. Kendall's expert report and references. See Pet. Exs. 65-92, filed Dec. 21, 2011.

J. Preparations for Hearing.

On January 13, 2012, I held a status conference with the parties to discuss any additional expert reports they intended to file. See Order, issued Jan. 13, 2012, at 1 (ECF No. 151). Petitioners indicated that they wanted to obtain an expert on pediatric development and an expert on oxidative stress. I discussed dates by which the parties should have all expert reports filed and indicated that the case should be ready for a hearing in November 2012. *Id.* I ordered the parties to discuss potential hearing dates with their experts and to propose dates for a hearing. *Id.*

Respondent proposed two weeks in February 2013, but petitioners failed to convey their preferred dates. See Order, issued Feb. 2, 2012 (ECF No. 152). Once petitioners concurred with respondent's proposed hearing dates, I set the hearing for February 17-27, 2013, in Washington, DC. Pre-Hearing Order, issued Feb. 3, 2012 (ECF No. 154).

On March 14, 2012, respondent filed expert reports responsive to Dr. Kendall's opinions from Bruce H. Cohen, M.D. and Kendall B. Wallace, Ph.D. See Res. Exs. SS-VV.

From late February to July 2012, petitioners filed a series of status reports detailing their efforts to find experts in the areas of oxidative stress and child development. In June, petitioners informed me that A.K.'s pediatrician, Dr. Heddy Zirin,³⁵ would be testifying in this case but they still were seeking a medical expert in

³³ See Res. Ex. LL (ECF No.145) (testimony from several OAP witnesses explaining autism spectrum disorders); Respondent's Second Rule 4 Report (ECF No.146), recommending against compensation.

³⁴ I had permitted respondent to defer filing her expert reports until after Dr. Kendall's report was filed. Scheduling Order, issued Oct. 24, 2011, at 1 (ECF No. 148).

³⁵ Doctor Zirin never testified. Petitioners indicated at the April 9, 2013 pre-hearing status conference that they did not intend to call her.

oxidative stress. Status Report, filed Jun. 1, 2012, at 1 (ECF No. 158). The following month, petitioners informed me that Richard Deth, Ph.D. would be testifying as an expert in oxidative stress and Mary Megson, M.D. would be testifying as a developmental pediatrician. Status Report, filed Jul. 31, 2012, at 2 (ECF No. 160).³⁶ Petitioners also informed me that the hearing, which had been set six months earlier, would have to be delayed. They explained that their attorney was lead counsel in a civil case in Nevada which the judge had “set a firm trial date” which conflicted with the hearing date for this case.³⁷ *Id.* at 1.

Ultimately, I bifurcated the hearing in this case, setting a fact hearing to take the testimony of petitioners and treating physicians in New York City, NY on December 12-13, 2012 and setting the entitlement hearing at which experts would testify in Washington, DC for April 22-30, 2013. Pre-Hearing Order, issued Aug. 16, 2012, at 2 (ECF No. 166). I ordered petitioners to file all expert reports by September 14, 2012 and respondents to file all expert reports by November 13, 2012. *Id.*

Once again, petitioners did not file their reports by the deadline I had imposed. Expert reports from Drs. Megson and Boris were filed on September 26, 2012 and from Dr. Deth on October 29, 2012. See Pet. Exs. 107-108; 117, Tabs 1-55. Since I had extended petitioners’ deadline for filing their expert reports, I adjusted respondent’s deadline, ordering her to file all expert reports by December 13, 2012. See Order, issued Sept. 26, 2012 (ECF No. 172).

K. The December 2012 Fact Hearing.

I ordered the parties to file their pre-hearing submissions for the fact hearing by November 9, 2012. Pre-Hearing Order, issued Sept. 26, 2012 (ECF No. 173). At the December 2012 hearing, I heard testimony from petitioners, [A.K.’s mother and father].³⁸ Ms. Sturm represented petitioners at the hearing.

³⁶ Petitioners attached CVs for Drs. Deth and Megson to their status report. See Pet. Exs. 95-96.

³⁷ On August 1, 2012, I held a status conference to discuss the scheduling conflict. See Order, issued Aug. 1, 2012 (ECF NO. 161). I reminded petitioners that I “deliberately set the hearing a year in advance to give the large number of experts who are expected to testify ample time to make the necessary arrangements in their clinical practices and research schedules to permit their presence at the hearing.” *Id.* Furthermore, I “expressed my concern that petitioners’ counsel failed to inform the trial judge of the previously set firm hearing date in this case when the jury trial date was being discussed” in the other case. *Id.* I ordered the parties to file a joint status report, discussing whether the entitlement hearing could be held from February 25, 2013 until March 5, 2013 and to determine if we could hear fact witnesses in December 2012 or January 2013, to shorten the time needed for the entitlement hearing itself. *Id.* To say I was concerned by Mr. McHugh’s cavalier disregard of the schedule in this case would be an understatement. Juggling schedules of experts frequently delays Vaccine Act cases, and this case had about three times the number of experts generally appearing.

³⁸ Two days prior to the hearing, petitioners informed me that due to time constraints for both Dr. Boris and [A.K.’s mother], Dr. Boris would not be testifying at the fact hearing. Instead, he would be testifying as both a fact and expert witness at the entitlement hearing in April 2013 in Washington, DC. Petitioners also decided against calling Dr. Zirin. See Supplemental Pre-Hearing Order, issued Apr. 17, 2013 (ECF No. 239).

During [A.K.'s mother's] testimony, it became apparent that petitioners thought they had filed documentation regarding A.K.'s receipt of a second dose of influenza vaccine³⁹ in early December 2001. Tr. at 69-70. I recessed while a copy of this record (filed later that day as Pet. Ex. 118) was obtained. Tr. at 70-71; see Pet. Ex. 118, filed Dec. 12, 2012 (ECF No. 188).

L. Second Request for Pre-Payment of Interim Fees and Costs.

Following the fact hearing, petitioners filed their second motion for interim costs. Arguing that they had expended \$17,000.00 litigating their claim, petitioners requested \$81,750.00 to cover costs they expected to incur during the April 2013 entitlement hearing. Motion, filed Jan. 10, 2013, at 3-5, 11 (ECF No. 190). The parties were unable to agree on an award of interim costs, but respondent indicated that she would not object to an award of interim fees and costs in the amount of \$30,000.00, representing payment for attorneys' fees. Status Report, filed Mar. 22, 2013, at 1-2 (ECF No. 209). On March 27, 2013, based on the documentation submitted for amounts already expended, I awarded interim costs in the amount of \$24,108.12. Decision (ECF No. 215). Neither party filed a motion for review of that decision.

M. Preparation for the April 2013 Entitlement Hearing.

On February 21, 2013, I ordered the parties to file any additional exhibits and medical literature by March 22, 2013, and pre-hearing briefs by April 8, 2013. Respondent filed their medical literature on March 22, 2013. See Res. Exs. MM, Tabs 20-24; OO, Tabs 1-4; SS, Tabs 1-20; UU, Tabs 17-20; VV. Indicating that they would be filing over 100 additional medical journal articles, petitioners requested an extension of four days. Motion, filed Mar. 22, 2013, at 1 (ECF No. 210). I granted petitioners' request but warned them that I would not consider additional literature filed after that date. Order, issued Mar. 25, 2013, at 1 (ECF No. 214); see *also* Pre-Hearing Order, issued Feb. 21, 2013, at 1 (ECF No. 199) (indicating that, absent a compelling reason, I would not consider late filed medical literature). Petitioners filed their medical literature on March 26, 2013.⁴⁰

A few days later, petitioners filed an unpublished paper regarding the evaluation and treatment of patients with autism and mitochondrial disorders from Dr. Richard Kelley at the Kennedy Krieger Institute. This document was not a medical journal article or medical record; it appeared to be a handout provided to patients or perhaps to referring physicians. See Pet. Ex. 233, filed on Mar. 31, 2013. Because I had given petitioners more than adequate notice that, absent a compelling reason, I would not

³⁹ At that time, children under two years of age received a split dose of vaccine, half the amount administered to older children and adults, in two vaccinations about one month apart.

⁴⁰ The articles filed were labeled as exhibits 124-67, 171-209, and 211-31. Petitioners correctly noted that exhibit numbers 169-70 and 210 had been assigned to previously filed exhibits. See Pet. Exs. 169-70, 210, filed on Mar. 22, 2013 (ECF No. 211) (attachments to petitioners' status report regarding interim costs).

consider medical literature filed after the deadline, I ordered the exhibit struck.⁴¹ Order, issued Apr. 9, 2013; see *also* audio transcript of Apr. 9 2013 status conference at 2:35 (petitioners' counsel agreeing that the article was "not critical" and that there was no compelling reason for the late filing).

Also on March 31, 2013, petitioners also filed a motion requesting that I issue a subpoena to compel an expert in another case to produce his expert report from that case and any other material or information "deem[ed] appropriate to accomplish the purposes of the Vaccine Act and justice." Motion to Issue Subpoena, filed Mar. 31, 2013, at 7 (ECF No. 216). I ordered respondent to file a response to petitioners' motion by April 8, 2013, reiterating that the parties' pre-hearing submissions were due on the same date. Order, issued Apr. 1, 2013 (ECF No. 218). Respondent filed her response (see ECF No. 224). I orally denied the motion. Apr. 9, 2013 status conference at 2:33.

On April 1, 2013, just three weeks prior to the start date for the causation hearing, petitioners requested leave of court to file a second amended petition. Motion, filed Apr. 1, 2013, at 1 (ECF No. 219). Petitioners attached the proposed amended petition as Pet. Ex. 234. I granted this motion and the amended petition ["2d Amend. Petition"] was filed on April 17, 2013 (see ECF No. 237); see *also* Apr. 9, 2013 status conference at 2:33-34 (permitting filing of the amended petition, but noting that petitioners were now alleging as causal vaccines that were not on the Vaccine Injury Table at the time their short-form petition was filed).

Petitioners then requested leave of court to file a recently published medical journal article.⁴² Because the article was not available until January 25, 2013, I granted petitioners' motion. Petitioners filed the article on April 17, 2013. See Pet. Ex. 235 (ECF No. 238); see *also* Apr. 9, 2013 status conference at 2:36-38 (permitting the late filing, despite the earlier on-line availability of the article).

The parties filed their pre-hearing submissions on April 8, 2013. ECF Nos. 225-26, 228-29. Additionally, petitioners filed another document (titled as a motion *in limine*) containing numerous requests for relief. See Motions *in Limine*, filed Apr. 8, 2013 (ECF No. 227). Because the deadline for respondent's response to petitioners' motions fell on the first day of the planned hearing, I extended respondent's deadline until two weeks after the hearing was scheduled to conclude. Order filed Apr. 9, 2013. I discuss and rule on these motions in Section II, below.

I held a status conference on April 9, 2013 to discuss preparations for the upcoming hearing. Following the call, respondent filed the updated CV for Dr. Raymond (see Res. Ex. NN, filed Apr. 10, 2013 (ECF No. 231)) and a status report listing the videotape clips she intended to use at the hearing (see Status Report, filed Apr. 12,

⁴¹ I reviewed the document prior to ordering it struck.

⁴² When petitioners originally filed their motion, they incorrectly used the exhibit number already assigned to their second amended petition (Pet. Ex. 234). See Motion, filed Apr. 4, 2013 (ECF No. 222). Thus, petitioners later asked that I strike that motion and allow the article to be filed out of time as exhibit 235. Motion, filed Apr. 9, 2013, at 3 (ECF No. 230).

2013 (ECF No. 232)). Petitioners filed the redacted videotape footage they intended to use at the hearing. See Notice filed Apr. 12, 2013 (ECF No. 233) (listing Pet. Exs. 236 and 236A).⁴³ Petitioners also filed the declaration of the technician who prepared the redacted videotape footage. See Pet. Ex. 237, filed Apr. 18, 2013 (ECF No. 241).

N. The April 2013 Entitlement Hearing.

Two days before the entitlement hearing, petitioners requested leave to file out of time a recently published article related to the research being conducted by one of their experts, Dr. Deth. Motion, filed Apr. 20, 2013 (ECF No. 243) (requesting to file Pet. Exs. 238 (article) and 238A (article's abstract)). I granted that request.

During the second day of the hearing, petitioners filed copies of the slides which Dr. Deth would be referencing while testifying and another recently published article upon which he intended to rely. See Pet. Exs. 239 and 240, filed Apr. 24, 2013 (ECF Nos. 244 and 245). The evening before the last day of the hearing, petitioners filed a motion for leave to file out of time another recently published article. See Motion, filed Apr. 28, 2013 (ECF No. 255) (requesting to file Pet. Ex. 241).⁴⁴

Respondent filed the updated CV of Dr. Cohen and copies of the presentations used by Drs. Jones, Johnson, and Raymond. See Res. Exs. TT, Tab 1; GGG; HHH; III.

O. Post Hearing Motions and Briefs.

Following the entitlement hearing, I ordered petitioners to file the medical literature referenced at hearing indicating that I “may or may not consider these articles but must see the entire article before making that determination.” Order, issued May 1, 2013, at 1 (ECF No. 257). This order was necessary because Dr. Deth cited many medical journal articles not previously filed on the PowerPoint slides he used during his testimony. I also allowed respondent to respond to the late-filed exhibits. *Id.*

Because petitioners informed me they had found an expert in child development to replace Dr. Megson, who had been unable to testify due to illness, and estimated they could file a report from their new expert within 60 days, I set a deadline for the replacement expert's report and a deadline 30 days thereafter for a written response

⁴³ Petitioners filed the notice of intent to file this video footage (on a computer hard disk) on April 12, 2013. Notice (ECF No. 233). However, the docket did not reflect receipt of the hard disk and no copy of it was received at OSM from the Clerk of Court. The original court file in this case did not contain a hard disk. Nevertheless, I was able to view the videos discussed at the hearing. In anticipation of issuing this ruling and the entitlement decision in this case, I ordered petitioners to file another copy of the video clips shown at the hearing to ensure that the record is complete. See Order, issued Aug. 20, 2015 (ECF No. 315). Based on the information supplied by petitioners, it appears that the hard disk was received, but somehow misplaced by the Clerk's Office. See Status Report, filed Aug. 20, 2015 (ECF No. 317). Pursuant to my order, petitioners provided another copy of the videos (this time on a jump drive) on Aug. 21, 2015. See Notice, filed Aug. 20, 2015 (ECF No. 318).

⁴⁴ Petitioners originally filed their motion on April 27, 2013 but asked that I strike that motion on April 28, 2013. See ECF No. Nos. 253 and 254.

from respondent. Order, issued May 1, 2013, at 1-2 (ECF No. 257). Petitioner later filed a status report indicating they “w[ould] not be submitting another expert’s report and will rely upon those submitted.” Status Report, filed July 1, 2013 (ECF No. 272). They then asked that Dr. Megson be allowed to testify by video in late summer or fall (see Status Report, filed July 17, 2013, at 1 (ECF No. 274)) but changed their minds approximately two weeks later, citing excessive costs and indicating they would rely on Dr. Megson’s expert report (see Status Report, filed July 30, 2013 (ECF No. 275), without the need for further testimony.

Finally, I reiterated my instructions at the close of the hearing that I would order the parties to file simultaneous post hearing briefs once the record was complete and reminded respondent that her deadline to respond to petitioners’ motions *in limine* was May 14, 2013. Order, issued May 1, 2013, at 1-2 (ECF No. 257). Respondent filed her response on May 13, 2013 (see ECF No. 258).

On May 31, 2013, petitioners filed the medical literature referenced in Dr. Deth’s PowerPoint presentation but, instead of assigning each article a new exhibit number, petitioners labeled them as references to the slide in which the article was mentioned. See (ECF No. 260-262). I ordered petitioners to assign each article its own exhibit number and to file an updated exhibit list reflecting the new exhibit numbers. Order, issued June 6, 2013, at 1-2. Petitioners filed their updated exhibit list assigning exhibit numbers 242-266 to the medical literature on June 25, 2013. See ECF No. 271.

Less than one month later, petitioners sought in a status report to file yet another article out of time. They assigned the article an exhibit number which had been used previously (Pet. Ex. 237). Status Report, filed July 17, 2013 (ECF No. 274). Because petitioners later filed an appropriate motion, albeit out of time, to file the same article, correctly labeled as exhibit 273, (see Motion, filed Apr. 24, 2013 (ECF No. 293)), petitioners’ July 17, 2013 request via status report to permit the late filing of medical literature is moot.

In August 2013, respondent filed the supplemental report of Dr. Johnson pertaining to the medical literature, previously unfiled, that Dr. Deth had referenced in his slide presentation at the hearing. See Res. Ex. JJJ. At that point, I filed Court Exhibit [“Court Ex.”] I, and solicited any comments, supplemental expert reports or arguments concerning the filing.⁴⁵ Order, issued Sept. 3, 2013 (ECF No. 277). I also set deadlines for filing any additional evidence in this case. Post Hearing Order, issued Sept. 9, 2013, at (ECF No. 278). Respondent filed supplemental expert reports from Drs. Cohen and Wallace responding to the Wolf & Smeitink article, Court Ex. I. See Res Exs. KKK, LLL, filed Sept. 30, 2013 (ECF No. 279). Petitioners filed a supplemental expert report from Dr. Kendall responding to Court Ex. I, but again re-

⁴⁵ N. Wolf & J. Smeitink, *Mitochondrial Disorders: A proposal for consensus diagnostic criteria in infants and children*, NEUROL. 59: 1402-06 (2002) [hereinafter “Wolf & Smeitink, Court Ex. I”]. Strictly speaking, it was unnecessary to file this document as a court exhibit, as it had been filed by respondent as Res. Exs. SS, Tab 19 and UU, Tab 15. However, I wanted both parties to address the diagnostic criteria specific to children set forth in the article and in the supplemental materials referenced in the article.

used an exhibit number. See Pet. Ex. 238, filed Oct. 3, 2013 (ECF No. 280). Petitioners also filed a written response from Dr. Deth to comments made by Dr. Johnson, once again assigning the response an exhibit number which had been previously used. See Pet. Ex. 239, filed Oct. 8, 2013 (ECF No. 281). Later, on January 16, 2014, petitioners moved to strike and replace Dr. Kendall's supplemental expert report, labeling it as Pet. Ex. 269 (see ECF No. 287). Thus, although there are no longer two exhibits labeled Pet. Ex. 238, there are still two exhibits labeled Pet. Ex. 239.

On November 15, 2013, I indicated that the evidentiary record was complete and ordered the parties to file post hearing briefs. Post Hearing Order (ECF No. 282).

Following my order, petitioners attempted to file four more articles out of time. See Motion, filed Jan. 14, 2014 (ECF No. 284) (requesting to file Pet. Ex. 240);⁴⁶ Motion, filed Apr. 24, 2014 (ECF No. 293) (requesting to file Pet. Exs. 271-73). Because I had ordered the evidentiary record closed in my November 15, 2013 order, I denied both of petitioners' motions. Order, issued Apr. 28, 2014, at 1-2 (ECF No. 294).

After multiple extensions of time, the parties filed their post hearing briefs on May 5, 2014. Petitioners attached a table setting forth multiple test results to their brief. See Pet. Ex. 274. Petitioners also requested that I strike the testimony of Dr. Miller, one of respondent's experts on autism diagnosis. Pet. Post-Hearing Memo, at 34 (ECF No. 297). I respond to that request in the rulings below.

The parties filed responses to the opposing party's brief on June 16, 2014. To their response, petitioners attached new three exhibits. See Pet. Ex. 274-275 and 279 (ECF No. 302). Petitioners again used an exhibit number (274) which had previously been used. The exhibit filed on June 16, 2014 is a notice of a funding opportunity for research regarding autism. See Pet. Ex. 274, filed June 16, 2015 (ECF No. 302).

After the filing of the post-hearing reply briefs, petitioners again requested to file out of time the four exhibits I had disallowed in April 2014 (see Order, issued Apr. 24, 2014, ECF No. 294), the three exhibits attached to their response to respondent's post hearing brief, and six additional articles. Motion, filed June 17, 2013 (ECF No. 303); Motion, filed June 26, 2014 (ECF No. 306).⁴⁷ In July 2014, respondent filed a response to petitioners' motions and petitioners then filed a reply.

⁴⁶ Petitioners originally filed an "unprocessed copy of Exhibit 240" but attempted to correct their mistake in an errata filed that same day (Errata, filed Jan 14, 2014 (ECF No. 285)) and then made a motion to strike (Motion, filed Jan. 14, 2014 (ECF No. 286)). Another article labeled Pet. Ex. 24 (Wong) had been used during the hearing. Petitioners eventually relabeled the Rose article (the subject of the abortive filings in January 2014) as Pet. Ex. 270.

⁴⁷ Originally, [A.K.'s father] filed this motion. See Motion, filed June 26, 2014 (ECF No. 305). Since he was not the attorney of record, I struck his filing. See Non-pdf Order, filed June 27, 2014.

II. Rulings on Outstanding Motions.

A. Overview.

With regard to most of the motions filed prior to the hearing in this case, I either ruled orally or deferred ruling until I could consider the proffered evidence in context of the testimony and other evidence properly filed. In orally denying the motion to subpoena an expert witness, see audio transcript at 2:33 (Apr. 9, 2013 status conference), I indicated that I would issue a written ruling at a later time.

Although petitioners characterized their motions as motions *in limine*, most were not motions to preclude the use of evidence. See BLACK'S LAW DICTIONARY (10th ed. 2014) (defining a motion *in limine* as a "pretrial request that certain inadmissible evidence not be referred to or offered at trial."). Rather, petitioners sought many different types of relief. Most of these motions were filed on April 8, 2013, at a time when both respondent's counsel and I were engaged in preparation for a lengthy hearing involving multiple experts. Petitioners had also just filed a new petition "clarifying" the theory of causation, many of the medical journal articles they filed had not been discussed by their experts, and there were extensive medical records in this case. Given the deluge of filings and the imminent hearing, I deferred ruling on most motions until after the hearing, when respondent would have adequate time to consider and respond and I could consider the issues in the context of the evidence adduced at the hearing. See *generally*, recording of status conference held April 9, 2013, at 2:32.

Petitioners' penchant for filing multiple motions requesting the same relief and their impaired ability to properly file exhibits have needlessly complicated the docket in this case. Sorting out the exhibit numbers alone has consumed considerable time and effort. During an April 9, 2013 status conference, I told the parties that a ruling on petitioners' motions would be issued at the time of or before issuing a decision on causation. Audio Tr. at 2:32-33. As reflected below, their attempts to drag what happened in another Vaccine Act case—one decided and compensated as a Table injury—into the resolution of this causation in fact case, has fruitlessly complicated the resolution of their motions, as I must address the actual procedural history for both the instant case and the *Poling* case, No. 02-1466. What actually happened in *Poling* is far different from the *Poling* case they describe.

Petitioners' counsel did not appear to understand that closing the record (which was not done until long after the hearing) meant that no further evidence should be filed, absent truly extraordinary circumstances. Petitioners never adequately explained in any of their requests to file medical journal articles (and often, not even newly published articles) why reopening the record to consider this evidence was truly necessary to a fair trial or a just result. I cannot identify even one of the articles filed after the evidence closed that was not either cumulative of the evidence already presented or which was truly late-breaking and highly significant. The need to read, re-read, and compare late-filed journal articles to the evidence already filed (which included at least 100 journal articles that no expert ever mentioned in a report or testimony) has materially

contributed to the delay in issuing a decision in their son's case. As respondent has noted, perhaps that was petitioners' intent, in the vain hope that more delay would work in their favor.

I now issue the written rulings on all of petitioners' outstanding motions and clarify why some of the filed motions are now moot.

B. Resolving Issues Surrounding the *Poling* Case.

The motion to subpoena, depose, or otherwise compel the expert testimony of Dr. Andrew Zimmerman and the motion to compel respondent to concede the medical theory advanced by petitioners are both bound up in the issues presented in another OAP case, one brought by Dr. Jon Poling and his wife on behalf of their minor daughter.⁴⁸ Understanding the background of this other, widely publicized case is critical to placing petitioners' motions in the case at bar in context.

1. Background and History of the *Poling* Case.

Petitioners in this case (and at least one other case)⁴⁹ have formally argued that respondent's concession of entitlement to compensation in the *Poling* case, No. 02-1466,⁵⁰ renders the government unable to contest entitlement in theirs. Their claim that respondent should be judicially estopped from challenging their causation theory stems from the *Poling* case, which was settled in 2010 but conceded by respondent in 2008.

The facts of the *Poling* case and its relationship to this one are drawn from two pieces of evidence properly filed in the instant case: a medical journal article filed by both parties and a highly unusual commentary by the editor-in-chief of the medical journal in which the article first appeared. Additionally, I reference the publically-available docket entries in *Poling* and the posted rulings and decisions by the special master. See § 12(d)(4)(b), requiring decisions of the special master to be disclosed and the "E-Government Act," (see n.1, *supra*) (requiring reasoned rulings of courts to be publically available).

⁴⁸ Although the minor's name has been disclosed publically, I will not use it in this ruling or in the entitlement decision to follow.

⁴⁹ See *Vernacchio v. Sec'y, HHS*, No. 08-504V, 2015 WL 1951051 (Fed. Cl. Spec. Mstr. Apr. 10, 2015). Of note, [A.K.'s father] is the counsel of record in *Vernacchio*. Although not raised via a motion regarding judicial estoppel, the *Poling* case and the Poling medical journal case report have been used by petitioners in several other cases alleging that a vaccine significantly aggravated or triggered a mitochondrial disorder or dysfunction, as evidence that a vaccine can do so. See, e.g., *Miller v. Sec'y, HHS*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Aug. 18, 2015); *Holt v. Sec'y, HHS*, No. 05-0136V, 2015 WL 4381588 (Fed. Cl. Spec. Mstr. June 24, 2015).

⁵⁰ In citations to the Pacer docket entries in *Poling*, I will identify the case name, the docket number and the ECF number for the filing at issue. With the exception of the publically available decisions and rulings in *Poling* (i.e., those appearing on the Court of Federal Claims website or WestLaw), none of the matters discussed herein with regard to *Poling* delve into the non-public filings. All other ECF numbers refer to matters filed in the instant case.

In October of 2002, Terry and Jon Poling filed a vaccine injury claim on behalf of their minor child. The child reportedly experienced symptoms of a developmental regression within 48 hours of a DTaP vaccination and more symptoms of a similar nature within five to 15 days of a measles vaccination, both of which were administered when the child was 19 months of age. The onset of neurological symptoms was within the periods for a DTaP Table encephalopathy (72 hours) and a measles Table encephalopathy (5 to 15 days). The child was eventually diagnosed with both autism and a mitochondrial disorder. Recognizing that the child experienced neurological symptoms within the time periods required for a Table injury, respondent filed a Rule 4(c) report⁵¹ conceding that petitioners were entitled to compensation.

The journal article, J. Poling, et al., *Developmental Regression and Mitochondrial Dysfunction in a Child With Autism*, J. CHILD NEUROL. 21:170-72 (2006), was filed by both parties.⁵² I cite to the copy filed as Res. Ex. MM, Tab 14 [hereinafter “Poling, Res. Ex. MM, Tab 14”]. The article contains a case study of a child who experienced a regression after receipt of several vaccinations and who thereafter experienced a loss of skills. This child was later diagnosed with autism and a mitochondrial disorder. The article also contains an abbreviated analysis of laboratory studies in 159 other children with ASD diagnoses, as compared to 94 children with neurological disorders other than ASD, with the stated purpose of demonstrating that other children with ASD diagnoses might also have mitochondrial disorders. Res. Ex. MM, Tab 14, at 171-72.

The commentary was filed as Res. Ex. MM, Tab 17: R. Brumback, *The Appalling Poling Saga*, J. CHILD NEUROL. 23(9): 1090-91 (2008). The commentary reflected that Dr. Jon Poling was the petitioner in a vaccine injury claim filed on behalf of his daughter. He and his co-authors failed to disclose that conflict of interest to the medical journal where the article was submitted and accepted for publication. The commentary reflected that a “media frenzy” had ensued when the decision to compensate the child’s vaccine injury case became public. The commentary’s focus was on the authors’ failure to disclose the pending injury claim as a conflict of interest. As Dr. Brumback noted: “Openness and transparency related to any and all potential conflicts of interest is critical to maintaining the integrity of science in general and of journal quality in

⁵¹ As a Vaccine Rule 4 report is “information submitted to a special master or the court in a proceeding on a petition,” it “may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.” § 12(d)(4)(A). Nevertheless, as discussed in more detail in Section II.B.3(b), *infra*, a copy of what purports to be the Vaccine Rule 4 report in *Poling* was filed by petitioners in this case as Pet. Ex. 57. I note that the public docket in *Poling*, No. 02-1466, contains an Amended Respondent’s Report, the contents of which do not appear to have been publically disclosed. See ECF No. 27, filed on February 25, 2008.

⁵² Petitioners filed versions of the article published online as Pet. Exs. 40; 63, Ref. 18; and 91. Curiously, in filing Pet. Ex. 40, petitioners identified it by the name of the last-listed author, Dr. Andrew Zimmerman, one of the Poling child’s treating physicians, rather than by the name of the first author, Dr. Jon Poling. Doctor Zimmerman is listed as the senior researcher (the last listed author) on the article. However, the principal author was Jon Poling, and another author was John Shoffner, the clinician who performed the mitochondrial disorder testing on A.K. *Id.* at 2. A third author was Dr. Frye, who was identified at one point as an expert in this case. The fourth author, Dr. Andrew Zimmerman, is the person petitioners sought to subpoena as an expert witness.

particular.” *Id.* at 1090.

Because the *Poling* case was settled, there was no entitlement decision explaining the basis for the action taken in it.⁵³ Instead, on March 6, 2008, the special master issued an order to proceed to a damages determination. *Poling*, 02-1466, ECF No. 35. In July 2010, respondent filed a proffer which Mr. and Mrs. Poling accepted. Shortly thereafter, then-Special Master Campbell-Smith, who presided over the *Poling* case through final resolution of the fees and costs in it, issued a decision awarding compensation in the amount agreed upon by the parties. See *Poling*, 02-1466, ECF Nos. 115, 117, 120, 127 (damages decisions and redacted and re-issued damages decision). In 2011, Special Master Campbell-Smith awarded attorney fees and costs in a published decision. *Poling v. Sec’y, HHS*, No. 02–1466V, 2011 WL 678559, at *1 (Fed. Cl. Spec. Mstr. Jan. 28, 2011). That decision reflects:

Respondent conceded that *petitioners are entitled to compensation based on a determination that [the minor child] suffered an injury identified on the Vaccine Injury Table, specifically, a presumptive MMR vaccine-related injury of an encephalopathy. [The child’s] encephalopathy eventually manifested as a chronic encephalopathy with features of an autism spectrum disorder and a complex partial seizure disorder as a sequela.*

Id. (emphasis added). The language emphasized makes clear that the *Poling* case was compensated based on the *presumption of causation that attaches when the Table injury requirements* are met, not on an actual causation or causation in fact basis. Otherwise, the reference to an injury appearing on the Vaccine Injury Table is nonsensical, as the only injuries that appear on the Table are those for which entitlement to compensation is presumed, such as the MMR Table injury of encephalopathy. See 42 C.F.R. § 100.3(a)(III)(B).

2. Connections between A.K.’s Case and *Poling*.

In their reply to respondent’s filing regarding the motion for reconsideration of my decision dismissing this petition for failure to prosecute, petitioners filed Pet. Ex. 57, a document “purporting to be the complete and entire Rule 4 Report filed by the respondent in *Poling*.” ECF No. 104 at 3. Petitioners requested disclosure of the actual Rule 4 report filed in *Poling* and the expert reports filed in that case, singling out a report by Dr. Andrew Zimmerman in particular. ECF No. 104 at 4, n.1. They characterized the Rule 4 report filed in *Poling* as constituting:

an admission that the conditions observed in [the minor child] are symptoms of mitochondrial disorder and that a vaccination of a person with that condition can cause symptoms similar to those evidencing autism. The respondent is estopped from taking any position in the instant

⁵³ Although respondent apparently conceded entitlement to compensation in her Rule 4 report in the *Poling* case, thereafter petitioner filed two expert reports in that case, including one by Dr. Andrew Zimmerman. See ECF Nos. 22 and 24, Case No. 02-1466.

case that is inconsistent with *the* [sic] *Poling* Rule 4 Report.

ECF No. 104 at 6.

Petitioners reiterated the arguments made in this reply brief when they filed the motion on April 8, 2013, seeking application of judicial estoppel or to compel respondent to admit the validity of their medical theory. See ECF No. 227. They reiterated their argument concerning their “right” to obtain a copy of Dr. Zimmerman’s report in the *Poling* case in their March 31, 2013 “Motion for Leave to Serve a Deposition Subpoena or Other Appropriate Relief, Including Disclosure of Relevant Evidence.”⁵⁴ ECF No. 216 at 1.

In her expert report and at the hearing, petitioners’ mitochondrial disease expert, Dr. Fran Kendall, placed considerable reliance on the *Poling* article, Res. Ex. MM, Tab 14. It was one of the two medical journal articles she cited in support of her theory that vaccines could cause or trigger a mitochondrial regression resulting in an ASD diagnosis. Pet. Ex. 65 at 7-8. She testified similarly. See Tr. at 254, 285-86. However, in testimony, she acknowledged that the facts in the *Poling* case report bore little resemblance to the facts in the case at bar. Tr. 367-71.

3. Issues Raised by Petitioners’ Reliance on *Poling*.

Petitioners’ reliance on the *Poling* case raises three issues in the instant case. The first is their use of documents barred by § 12(d)(4)(A) of the Vaccine Act. The second is their contention that Dr. Zimmerman can be compelled to offer expert testimony. The third is their judicial estoppel argument.

a. Filings in Violation of the Vaccine Act.

Section 12(d)(4)⁵⁵ of the Vaccine Act governs the disclosure of information

⁵⁴ This filing contains a troubling misstatement, in that it claims petitioners learned only *on March 30, 2013* that petitioners in *Poling* filed a report by Dr. Andrew Zimmerman. ECF No. 216 at 1. Their filing of November 6, 2010 (ECF No. 104) reflected that they were aware of such an expert report filing long before March 2013. *Id.* at 4, n.1.

⁵⁵ Section 12(d)(4) provides:

(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information--

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

submitted during a vaccine proceeding. The language of § 12(d)(4) is incorporated into Vaccine Rule 18. Congress added this section in amendments it made to the Vaccine Act in 1989. P.L. No. 101-239, 103 Stat. 2106.

The legislative history for the language prohibiting disclosure of information submitted during vaccine proceedings without written consent (which now appears at § 12(d)(4)(A)) was originally located at the end of the paragraph describing the special masters' discovery powers (§ 12(c)(2) (Supp. V 1988)). In the 1989 amendments, this non-disclosure provision, which abrogated the common law rule that court filings are open to public scrutiny, was moved to § 12(d)(4)(A) and the new directive requiring the disclosure of vaccine decisions was added in § 12(d)(4)(B). See H.R. Conf. Rep. 101-386, at 512-13 (1989), *reprinted in* 1989 U.S.C.C.A.N. 3018, 3115-16; see also *Castagna v. Sec'y, HHS*, No. 99-411V, 2011 WL 4348135, at *6-7 (Fed. Cl. Spec. Mstr. Aug. 25, 2011) (for a comprehensive discussion of the legislative history of the Vaccine Act and the 1989 amendments).

Under § 12(d)(4)(A), information submitted to a special master in a case may not be disclosed without the express written consent of the party who submitted the information. Thus, Congress protected any information submitted by a party from public view, effectively sealing pre-decisional Vaccine Act proceedings. This is a departure from the common law right of access to judicial records. See, e.g., *Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597 (1978) (remarking that “the existence of a common-law right of access to judicial records” is widely acknowledged, though as “[a]n infrequent subject of litigation, its contours have not been delineated with any precision.” The Court also stated that “[i]t is clear that the courts of this country recognize a general right to inspect and copy public records and documents, including judicial records and documents” (internal citations omitted).).

In spite of the explicit language in the Vaccine Act and Vaccine Rule 18, petitioners filed several documents in this case that they claim were filed in *Poling*: (1) the Rule 4 report (Pet. Ex. 57);⁵⁶ (2) a largely illegible two page document taken from a

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

⁵⁶ It does not appear that respondent has formally challenged the admissibility of the Rule 4 report from the *Poling* case filed as Pet. Ex. 57 in the instant case, although she may have addressed the issue obliquely in some filings. While this lack of formal challenge may not constitute the “express written consent” of the party who submitted this information, the lack of any objection, coupled with respondent’s reliance on matters contained in Pet. Ex. 57 in at least one document filed in this case (see ECF 308 at 8, n.8), leads me to treat respondent’s lack of objection as consent. I will also treat respondent’s citation to Pet. Ex. 57 as an implicit concession that the document is what it purports to be—a somewhat expurgated version of the Rule 4 report filed in the *Poling* case. Notwithstanding the public and highly improper disclosure of this Rule 4 report, Vaccine Rule 4 reports are not intended for public release, and as such are not drafted with the intent to explain in detail all of the considerations that may lead respondent to concede a case or to compensate a case based on a litigative risk assessment. The only way to enforce the clear statutory intent that what a party files remains exempt from public disclosure

website that appears to be a letter written by Dr. Zimmerman (Pet. Ex. 283); (3) a letter from Dr. Zimmerman to petitioners' counsel in *Poling* that appears to address the issue of sequela of the original Table encephalopathy, also obtained from a website (Pet. Exs. 284 and 285); (4) a mostly illegible copy of a PowerPoint slide which appears to be the last page of the Zimmerman letter, titled "Dr. Zimmerman's Second Medical Opinion Letter" (Pet. Ex. 286); and (5) another copy of the letter from Dr. Zimmerman to petitioners' counsel in the *Poling* case, dated November 30, 2007 (Pet. Ex. 277).

As articulated in their June 26, 2014 motion to reopen the record and file Dr. Zimmerman's report out of time (ECF No. 306), petitioners reiterated their claim that they learned of Dr. Zimmerman's report only on March 30, 2013. This claim is erroneous. See, *supra*, n.54. In their motion, they acknowledged that the matters filed in the *Poling* case remained sealed, speculating that they remained so in order "to secure a financial settlement for the severely injured minor petitioner."⁵⁷ ECF 306 at 8.

Noticeably lacking in the motion for leave to file Pet. Ex. 277 out of time (ECF No. 306) and in any of the other filings in this case is any suggestion that the petitioners in this case secured the "express written consent" of the persons who submitted Dr. Zimmerman's letter or respondent's Rule 4 report in *Poling*.

Another round of briefing ensued on this issue. See ECF Nos. 308, 309. Respondent noted that the timing of the filing of Dr. Zimmerman's expert report in *Poling* indicated that it was not the basis for respondent's concession, as the report was filed after respondent's first substantive Rule 4 report conceding the case.⁵⁸ See ECF No. 308 at 8, n.8. Petitioners argued that there was no impropriety in seeking to file Pet. Ex. 277 because it had "been published repeatedly on the internet, and ha[d] been presented more than once in public events." ECF No. 309 at 6-7. They argued that "fundamental fairness and due process of law" compel the admission of Dr. Zimmerman's report.

(except to the extent these matters are relied on in a special master's decision) is to preclude the filing of documents from one case in another case, absent that "express written consent." However, as respondent has used that Rule 4 report as a sword in this case, I will not preclude its use by petitioners. I therefore find petitioners' request for disclosure of the Rule 4 report in *Poling* (see ECF No. 104 at 4, n.1) moot as the evidence sought is already before me.

⁵⁷ Once again, a review of the publically available docket in *Poling* reveals that on July 20, 2009, petitioners filed a motion to withdraw a previously filed motion (ECF No. 86). After additional filings by both sides (see ECF Nos. 88 and 90), the presiding special master granted a "Motion for Appropriate Relief," filed by respondent on June 26 2008 (referencing ECF No. 61) and a granted "Motion to Withdraw Motion for Complete Transparency" filed by petitioners (referencing ECF No. 86). See Order issued Aug. 20, 2009 (ECF No. 92). The decision awarding damages was not issued until nearly a year later (July 21, 2010), which is hardly suggestive of a *quid pro quo*.

⁵⁸ Respondent filed an initial Rule 4 report in *Poling* in January 2003. It was likely a pro forma report reflecting that petitioners had not filed medical records sufficient for respondent to assess the case and objecting to the use of a short form petition, as both objections were commonly made in the OAP cases filed pursuant to Vaccine General Order #1. See *Poling* ECF No. 5. This assumption is borne out by the Order Deferring Ruling on Petitioners' Motion for Complete Transparency of Proceedings. *Poling*, 2008 WL 1883059, at *11-12.

b. Motions Regarding Dr. Zimmerman.

Leaving the issue of violations of § 12(d)(4)(A) aside temporarily, there are other issues surrounding the use of Dr. Zimmerman's report that are bound up with petitioners' requests to depose him or compel his appearance at the hearing in their son's case.

Petitioners first requested disclosure of Dr. Zimmerman's expert report in *Poling* in their reply to respondent's objection to petitioners' motion for relief from my decision dismissing their claim.⁵⁹ See ECF No. 104 at 4, n.1. They apparently believed that Dr. Zimmerman had filed a report that had affected respondent's decision to concede the *Poling* case, and argued that because *Poling* was "designated" as a test case, the waiver of the privacy provisions filed by petitioners in each of the actual test cases somehow applied to the *Poling* case as well.

Based on the OAP docket (<http://www.cofc.uscourts.gov/docket-omnibus-autism-proceeding>), as well as the docket in *Poling*, No. 02-1466, petitioners' assertions are factually incorrect. The *Poling* case was never formally designated as a test case, (*Poling*, 2008 WL 1883059, at *1-2), and the petitioners in that case consequently never filed that express written consent.⁶⁰

Given the procedural posture of this case at the time, I did not rule on petitioners' request, expecting that petitioners would retain experts and file their reports pursuant to my orders, likely obviating the need to decide whether production of the expert report was within my authority and necessary to a fair and just resolution of the issues.

Apparently unsatisfied by the experts they had obtained, on March 31, 2013, petitioners moved for leave to serve a subpoena on Dr. Zimmerman. Petitioners' Motion for Leave to Serve a Deposition Subpoena or Other Appropriate Relief, Including Disclosure of Relevant Evidence [hereinafter "Pet. Mot. for Subpoena"], filed Mar. 31,

⁵⁹ They also requested disclosure of the other expert reports filed in *Poling*, asserting that, as these expert reports were filed while the *Poling* case was under consideration as a test case, they should be as publically available as the reports in other test cases. Again, with reference to the public docket in *Poling*, No. 02-1466, there is no indication that any expert reports were filed in *Poling* prior to the government's concession in the November 2007 Rule 4 report. Pet. Ex. 57, the Rule 4 Report in *Poling*, does not reference any expert reports, referring only to the treatment and diagnostic records.

⁶⁰ The *Poling* case does appear on the "List of Potential Test Cases for May 2008 Hearings," the hearings in the Theory 2 test case as one of three cases being considered for test case designation. See Autism Master File, OAP docket, filing of Sep. 17, 2007, at 3. See <http://www.cofc.uscourts.gov/docket-omnibus-autism-proceeding>. The filing contained the disclaimer: "By filing these records and designating these claims as 'potential test cases,' neither claimant nor the PSC represent that any one petition will actually be designated for hearing in the May 2008 general causation proceedings." *Id.* at 1; see <http://www.cofc.uscourts.gov/docket-omnibus-autism-proceeding>. Once again, petitioners in the instant case either misconstrued or misstated what had occurred. I note that A.K.'s own case, which did not appear on the list of "potential test cases," was designated as a test case on January 8, 2008, via the filing of an expert report in the [*R.K. on behalf of A.K.*] case in the OAP docket on that date. "PSC's Expert Report in [*R.K. on behalf of A.K.*] Test Case" at 1; see <http://www.cofc.uscourts.gov/docket-omnibus-autism-proceeding>. The report was removed from the OAP docket when petitioners in [*R.K. on behalf of A.K.*] withdrew as a test case.

2013 (ECF No. 216). On close examination, the subpoena request was a thinly veiled attempt to *compel* Dr. Zimmerman to give expert testimony in this case, rather than testify as a percipient witness, treating physician, or retained expert. Later, petitioners conceded that they had contacted Dr. Zimmerman “and were informed that he would not testify as an expert except in cases in which he was the treating physician.” ECF 309 at 7-8 (Petitioners’ Reply Brief in support of their motions to reopen the record and judicial estoppel). Petitioners’ many filings on the Zimmerman subpoena issue are rife with misstatements or misunderstandings of the matters asserted. The facts (and their assertions) overlap to some extent with those in the estoppel motions. I thus address the background matters pertinent to both motions here.

c. Additional Background Information and Facts.

Petitioners claim that they only learned of Dr. Zimmerman’s report in *Poling* on March 30, 2013. ECF No. 216 at 1. This assertion is rebutted by their own earlier filing of November 6, 2010 (ECF No. 104), which reflected that they were aware of such an expert report filing long before March 2013. *Id.* at 4, n.1. *See* n.54 *supra*.

Petitioners’ claim that the *Poling* case involved a concession of causation based on Dr. Zimmerman’s report in *Poling* (ECF No. 216 at 3-4) is raised in several filings. *See, e.g.*, ECF No. 227 at 5, n.5 (referencing their request for Dr. Zimmerman’s report in ECF No. 216); ECF No. 227 at 15 (asserting that the Zimmerman’s report in *Poling* was a decisive factor in the decision to settle).⁶¹ The timeline and records in *Poling* reflect otherwise.

On November 9, 2007, respondent conceded petitioners’ entitlement to compensation in *Poling* in her Rule 4 report. *Poling* ECF No. 17; Pet. Ex. 57. Five days later, the presiding special master ordered a status conference “to discuss further proceedings to address damages.” *Poling* ECF No. 18. Doctor Zimmerman’s report was filed on December 13, 2007, more than a month after respondent’s Rule 4 report was filed. *Poling* ECF No. 24. Thus, the temporal relationship alone belies petitioners’ assertions that Dr. Zimmerman’s expert report resulted in the concession.⁶²

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⁶¹ This description may not be entirely inaccurate. Doctor Zimmerman’s report may have played a role in the amount of compensation petitioners in *Poling* ultimately received, because the first substantive Rule 4 report in *Poling* denied that the Poling child’s seizure disorder was related to the encephalopathy for which entitlement was conceded. The special master’s fees and costs decision reflected that the Poling petitioners were compensated for the seizure disorder as well as the other injuries that were conceded in the Rule 4 report. *Poling*, 2011 WL 678559, at *1.

⁶² As one of the Poling child’s treating physicians, it is possible and even likely, that opinions on connection or causation by Dr. Zimmerman were expressed in the child’s medical records. These do not constitute “expert reports,” and in any event such documents are not publically available, absent express written consent of the petitioners in the *Poling* case.

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Given that respondent’s amended Rule 4 report, filed on February 21, 2008 (*Poling*, No. 02-1466, ECF No. 27), has never been publically disclosed, the best evidence of why respondent conceded entitlement to compensation would be found in the special master’s decisions in that case. However, neither the special master’s order to proceed to a damages determination (*Poling*, No. 02-1466, ECF No. 35) (which is not, strictly speaking a “decision” based on the use of that term in the Vaccine Act), nor her decisions awarding damages (see *Poling*, No. 02-1466, ECF Nos. 115, 117, 120, and 127) are publically available under the name “Poling.”⁶³

As the special master assigned to *Poling* explained in her April 10, 2008 Order, Dr. Zimmerman’s report— [* * * * *] —was not filed until after respondent’s initial Rule 4(c) report. *Poling v. Sec’y, HHS*, No. 02-1466V, 2008 WL 1883059, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2008) (Order Deferring Ruling on Petitioners’ Motion for Complete Transparency of Proceedings). Because the facts demonstrate that Dr. Zimmerman’s report in *Poling* was filed *after* the case was conceded in the Rule 4 report, it could not possibly have been a factor in respondent’s decision to concede entitlement to compensation on the basis of a Table injury.

The unredacted attorney fees and costs decision filed on January 28, 2011, (see *Poling*, 2011 WL 678559) answers the question of why the *Poling* case was conceded. There, the special master clearly and unequivocally noted that the concession was based on the presence of a Table encephalopathy. When a prima facie case for a Table encephalopathy exists, causation is presumed. See 42 C.F.R. § 100.3; *de Bazan, v. Sec’y, HHS*, 539 F.3d 1347, 1354 (Fed. Cir. 2008) (citing *Knudsen v. Sec’y, HHS*, 35 F.3d 543, 548 (Fed.Cir.1994)). Such a presumption may not be rebutted by the presence of an “idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury illness, or condition.” §13(a)(2). The cause of most cases of ASD

⁶³ A redacted damages decision, *CHILD DOE/77 v. Sec’y, HHS*, 2010 WL 3395654 (Fed. Cl. Spec. Mstr. Aug. 27, 2010), was issued the same date that a redacted damages decision entry appears in the docket of the *Poling* case (*Poling* ECF No. 127). A perusal of the redacted decision suggests that these two cases are one and the same. However, I do not rely on the redacted *CHILD DOE/77* decision to determine why respondent conceded the *Poling* case, if, indeed, they are the same case.

is unknown, although genetic factors and prenatal influences are strongly suspected. *Dwyer*, 2010 WL 892250, at *29-36; *Snyder*, 2009 WL 332044, at *46-53. Thus, a “she has ASD” defense would not suffice to demonstrate alternate causation.

I find that the Zimmerman expert report was not what prompted the respondent to concede the *Poling* case. I find, consistent with the presiding special master’s published decision, that the *Poling* case was conceded based on the presence of a Table encephalopathy.

d. Issues Related to Concession, Conspiracy, and Concealment.

In numerous filings, petitioners have obstinately insisted that respondent, her agents, or other governmental officials have conceded the causation theory they have advanced.⁶⁴ They claimed that respondent deliberately conceded the *Poling* case to avoid having a special master rule on the issues presented, and thereafter concealed what had happened in *Poling*. These issues all feed into the judicial estoppel arguments.

Petitioners first asserted that respondent had, in effect, conceded their theory of causation in October of 2010, when they filed their Motion for Reconsideration and Relief from Order and Decision Dismissing Petition (ECF No. 100). In support of their argument that I restore their petition, petitioners provided a quotation⁶⁵ from Dr. Julie Gerberding, former Director of the Center for Disease Control, and stated that “[t]hus, mitochondrial dysfunction can generate autism-like symptoms.” Motion for Reconsideration (ECF No. 100) at 14.

In their subsequent Reply, filed November 6, 2010, petitioners took their admission argument a step further. They argued that “[t]he Rule 4 Report filed in *Poling* is a pleading in a prior proceeding and constitutes an admission that...a vaccination of a person with [a mitochondrial disorder] can cause symptoms similar to those evidencing autism.” Petitioners’ Reply to respondent’s Response to Motion to Reconsider, filed November 6, 2010, at 6 (ECF No. 104).

For the past five years, petitioners have repeatedly insisted that the government conceded the *Poling* petitioners’ theory of causation and is thus unable to contest their

⁶⁴ Petitioners are not always consistent about the causation theory they claim was “conceded.” See, e.g., Reply to Response to Motion for Reconsideration, filed Nov. 6, 2010, at 6 (ECF No. 104) (stating that the *Poling* Rule 4 report was an admission that vaccination of a person with a mitochondrial disorder can lead to symptoms of autism); Motion to Amend Schedule and Award Interim Cost of Expert Witness, filed Nov. 30, 2010, at 3 (ECF No. 109) (stating that the government had conceded a “mitochondrial encephalopathy”).

⁶⁵ Doctor Gerberding’s comments about the *Poling* case were prefaced by her statement: “I don’t have all the facts because I still haven’t been able to review the case files myself.” Pet. Ex. 37 at 3. I note that she is a doctor, not a lawyer and, while she may have general medical knowledge about decompensation and regression in mitochondrial disorders, there is no evidence of her medical specialty. Saying that respondent is bound by an uninformed comment by a subordinate official is absurd. *Holt*, 2015 WL 4381588, at *29 n.80.

entitlement to compensation. Their arguments generally fell into six categories. First, they claimed that respondent has conceded the theory of causation in a party admission. See, e.g., Motion for Reconsideration (ECF No. 100), Reply (ECF 104), Petitioners' Motions *in Limine*, filed Apr. 8, 2013 (ECF No. 227), Prehearing Submissions, filed Apr. 8, 2013 (ECF No. 228), Motion for Leave to File Exhibits, filed Jun. 17, 2014 (ECF No. 303). Second, they insinuated that respondent purposefully avoided an adverse ruling in *Poling* by removing it from the OAP and attempting to prevent the disclosure of any facts to the public, implying that respondent's actions were in some way underhanded. See, e.g., Motion to Issue Subpoena, filed Mar. 31, 2013 (ECF No. 216), Motions *in Limine* (ECF No. 227), Reply to Motions *in Limine*, filed May 20, 2013 (ECF No. 259), Supplemental Motion for Leave to File Exhibits, filed Jun. 26, 2014 (ECF No. 306).⁶⁶ This argument, which is completely unfounded, entirely mistakes the progression of events surrounding the *Poling* case.⁶⁷ Their third argument was that courts have already accepted their causation theory. See, e.g., Motions *in Limine* (ECF No. 227), Post-Hearing Brief, filed May 5, 2014 (ECF No. 297), Motion for Leave to File Exhibits (ECF No. 303), Supplemental Motion for Leave to File Exhibits (ECF No. 306). Fourth, they argued that Dr. Zimmerman's expert report from the *Poling* case directly led to that case's concession.⁶⁸ See, e.g., Motion to Amend Schedule, filed Nov. 30, 2010 (ECF No. 109), Motions *in Limine* (ECF No. 227), Supplemental Motion for Leave to File Exhibits (ECF No. 306). Fifth, they insisted that it is fundamentally unfair for the government to be allowed to take an inconsistent position in this case, given their concession of *Poling*. See, e.g., Motions *in Limine* (ECF No. 227),

⁶⁶ In this filing, petitioners asserted that the government may have suppressed information regarding vaccine safety. ECF 309 at 9.

⁶⁷ Petitioners in *Poling* filed a "Motion for Complete Transparency of Proceedings" on March 4, 2008. On April 10, 2008, then-Special Master Campbell Smith issued a published Order Deferring Ruling on Petitioners' Motion for Complete Transparency of Proceedings, No. 02-1466V, 2008 WL 1883059 (Fed. Cl. Spec. Mstr. Apr. 10, 2008). Special Master Campbell-Smith provided an exhaustive history of the matter and ultimately concluded that any public disclosure of case materials, including the Rule 4 Reports, would, under § 12(d)(4)(A) of the Vaccine Act, require the consent of the parties. When she issued her Order, the parties had "been unable to execute a signed consent form." *Id.* at *11. She encouraged the parties to execute such a form given their "expressed willingness" to do so and provided the parties with 60 days within which to come to an agreement. *Id.* Apparently, the parties never managed to resolve the issue, as the *Poling* docket indicates that more than a year later, Special Master Campbell-Smith ordered petitioners to file a motion withdrawing their motion for complete transparency by July 22, 2009 (ECF No. 85). On July 20, 2009, petitioners filed a "Motion to Withdraw Previously Filed Motion" (ECF No. 86), which presumably was the motion for complete transparency. Special Master Campbell-Smith's Order and the publically available *Poling* docket entries make clear that both respondent and petitioners were interested in complete public disclosure of all of the facts and records related to the *Poling* case. Had the parties managed to execute a signed consent agreement in accordance with § 12(d)(4)(A) of the Vaccine Act, petitioners' motion likely would have been granted. Contrary to petitioners' claims in the instant case, respondent did not purposefully prevent the public disclosure of the *Poling* Rule 4 Reports. (It is worth noting that Rule 4 Reports are customarily never publically disclosed, so respondent's willingness to disclose the *Poling* Rule 4 Reports, contingent upon petitioners' permission, was rather extraordinary. If anything, this indicates that respondent was very interested in the public dissemination of the *Poling* case materials.)

⁶⁸ Respondent contested petitioners' statement that *Poling* was settled in part because of the expert reports. In her Response, respondent stated that compensation in that case was not based on expert reports. Respondent's Response, filed Dec. 14, 2010 (ECF No. 113), at 2, n.1.

Reply to Motions *in Limine* (ECF No. 259), Motion for Leave to File Exhibits (ECF No. 303), Supplemental Motion for Leave to File Exhibits (ECF No. 306). And finally, they argued that the government has a duty to the public to provide evidence in support of petitioners' theories. See, e.g., Motion to Issue Subpoena, filed Mar. 31, 2013 (ECF No. 216), Supplemental Motion for Leave to File Exhibits (ECF No. 306), Reply to Response to Supplemental Motion for Leave to File Exhibits, filed Jul. 14, 2014 (ECF No. 309).

Petitioners in the instant case asserted that Dr. Zimmerman's testimony would support the medical theory that they advanced and sought to compel his expert opinion. See *generally* Pet. Mot. for Subpoena (ECF No. 216). Petitioners did not cite any legal authority that would empower me to compel an expert witness to provide an opinion, nor did they assert that Dr. Zimmerman had ever met, let alone treated, A.K.

Respondent filed her response on April 8, 2013. She correctly noted that the Vaccine Act does not provide petitioners a right to discovery (see Response at 1-2 (ECF No. 224); see also 42 U.S.C. § 300aa-12(d)(3)(B)), and, further, that petitioners did not demonstrate how subpoenaing Dr. Zimmerman would lead to any information relevant to their case. See Response at 3-4.

4. Legal Standards and Analysis.

a. Standard for Compelling Discovery and Expert Witness Testimony.

Under the rules for civil procedure governing litigation in the Court of Federal Claims and other federal courts, a judge may authorize a subpoena to an expert witness. However, this authority is rarely invoked or granted. See *Resource Investments, Inc. v. U.S. [Resource II]*, 93 Fed. Cl 373, 378 (2010). “[A]lthough it is not the usual practice, a court does have the power to subpoena an expert witness and, though it cannot require him to conduct any examinations or experiments to prepare himself for trial, it can require him to state whatever opinions he may have previously formed.” *Carter-Wallace, Inc. v. Otte*, 474 F.2d 529, 536 (2d. Cir. 1972). See also *Kaufman v. Edelstein*, 539 F.2d 811 (2d. Cir. 1976) (an antitrust case determining that an expert may be called against his will if “[a] substantial part of the testimony which the Government...seeks...is testimony no one else can give.”).

These rules do not govern discovery in Vaccine Act proceedings, but the cases interpreting them may be helpful in understanding why such subpoenas are limited to unusual factual situations. The Vaccine Act provides that rules for proceedings under the Act shall “provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.” §12(d)(2)(E). They further provide the presiding special master the authority to “require such evidence as may be reasonable and necessary” and to “require the testimony of any person and the production of any documents as may be reasonable and necessary.” § 12(d)(3)(B)(i) and (iii).

Courts have, on occasion, subpoenaed an expert witness who already has

critical information about a pending case. But if an expert is not willing to opine and is not already familiar with the case, courts have held that he should not be subpoenaed. See, e.g., *Buchanan v. Am. Motors Corp.*, 697 F.2d 151 (6th Cir. 1983) (holding that the district court did not err in quashing a subpoena for an expert witness who was a stranger to the litigation). Courts are generally discouraged from subpoenaing expert witnesses. See, e.g., Fed. R. Evid. 706 (stating that although a court may appoint an expert witness, it “may only appoint someone who consents to act.”). As Judge Block has noted, “expert testimony is ordinarily a matter of private contract and may not be compelled.” *Resource II*, 93 Fed. Cl. at 378. An expert witness “is ordinarily not the proper subject of a subpoena.” *Id.* at 383.

Parties to a case authorized by the Vaccine Act are not entitled to formal discovery; informal exchanges of relevant information are preferred. Rule 7(a). Should a party determine that informal discovery is inadequate, “the party may move the special master...to employ any of the discovery procedures set forth in RCFC 26-37.” Rule 7(b)(1). Any such motion must include “the discovery sought and state with particularity the reasons therefor, including an explanation as to why informal discovery techniques have not been sufficient.” Rule 7(b)(2). Upon a party’s request, a “special master *may* approve the issuance of a subpoena pursuant to RCFC 45.” Rule 7(c) (emphasis added).

Court of Federal Claims Rule 45 explains the procedures required for the issuance of a subpoena, but notes that the court may quash a subpoena if it requires “disclosing an unretained expert’s opinion or information that does not describe specific occurrences in dispute and results from the expert’s study that was not requested by a party.” RCFC 45(d)(3)(B). Notwithstanding a judicial officer’s discretion to quash or modify a subpoena in such circumstances, the court may elect to order appearance or production if two criteria are met: (1) the serving party “shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship;” and (2) the serving party “ensures that the subpoenaed person will be reasonably compensated.” RCFC 45(d)(3)(C).

b. Application to This Case.

Although a court may, when circumstances warrant, compel an expert to provide testimony, this is a significant departure from the general rule that an expert witness should not be compelled to testify. See *Resource II*, 93 Fed. Cl. at 378. Courts are reluctant to subpoena expert witnesses unless they already have critical information related to the case at bar. See *Buchanan*, 697 F.2d 151. Absent extraordinary circumstances, it is inappropriate to approve a subpoena for an expert witness who is not willing to opine.

Under RCFC 45(d)(3)(B), I may quash a subpoena that would require the disclosure of “an unretained expert’s opinion...that does not describe specific occurrences in dispute and results from the expert’s study that was not requested by a party.” Doctor Zimmerman’s report in the *Poling* case does not describe “specific

occurrences in dispute” in the instant case. [* * * * *] Moreover, as Dr. Zimmerman has never treated A.K., he has no familiarity whatsoever with the case at bar. And, as petitioners’ own expert conceded at trial (Tr. 368-71), the facts of A.K.’s case bear no resemblance to those in the *Poling* case. Thus, RCFC 45(d)(3)(B) overwhelmingly favors denying petitioners’ request for a subpoena for Dr. Zimmerman.

5. Denying Subpoena.

Although a subpoena for expert testimony may be appropriate in some extraordinary circumstances, they do not exist here, where Dr. Zimmerman has never treated A.K. and has declined to offer an expert opinion. RCFC 45(d)(3)(C) empowers me to, in my discretion, order the testimony of a witness if petitioners have a “substantial need for the testimony” that they could not otherwise obtain “without due hardship” and petitioners ensure that the witness will be “reasonably compensated.” Petitioners have made no such showing.

Furthermore, I do not find such action to be reasonable and necessary to a fair and just resolution in this case. Petitioners produced a qualified expert (Dr. Fran Kendall) who opined that vaccines can trigger or aggravate an underlying mitochondrial disorder. Even if Dr. Zimmerman’s testimony would buttress that of Dr. Kendall (and, his willingness to testify only in cases in which he has been a treating physician suggests that his opinions are narrower and more nuanced than petitioners claim), it is not reasonable or necessary in this case.

In my discretion, I find that petitioners have not demonstrated a need for Dr. Zimmerman’s testimony about an unrelated case alleging a somewhat similar injury caused by different vaccinations. **Their motion for a subpoena is DENIED.**

6. Judicial Estoppel.

a. Background of the Motions.

Petitioners requested that I issue an order either compelling respondent “to admit that a vaccine can cause significant aggravation of a pre-existing mitochondrial disorder which may manifest[] as an encephalopathy with features of autistic spectrum disorder,” or to bar, “on the grounds of estoppel, respondent from denying that a vaccine can cause significant aggravation of a pre-existing mitochondrial disorder.” Motions *in Limine* at 20 (ECF No. 227).

Respondent filed her Response [hereinafter “Response to Motions *in Limine*”] to petitioners’ motion for judicial estoppel on May 13, 2013. Respondent argued that petitioners’ request was barred as a matter of law. Response to Motions *in Limine* at 1-2 (ECF No. 258). Additionally, respondent asserted that she never conceded that a

vaccine was capable of significantly aggravating a pre-existing mitochondrial disorder and, moreover, that the instant case differed from *Poling* in “many critical ways,” including the vaccine in question and the presence or absence of a Table injury. Response to Motions *in Limine* at 2-3 (ECF No. 258).

On May 20, 2013, petitioners filed a Reply to Respondent’s Response to their Motions *in Limine* [hereinafter “Pet. Reply”] in which they argued that respondent had “profoundly mischaracterize[d]” their motion for judicial estoppel (Pet. Reply at 1 (ECF No. 259)), focusing on collateral estoppel rather than judicial estoppel (*id.* at 5). Petitioners described the Rule 4(c) report respondent filed in *Poling* as “an admission by respondent in a pleading that vaccinations can aggravate an underlying mitochondrial disorder.” *Id.* at 3. Since they contend that their case was substituted for *Poling* as a test case once *Poling* was withdrawn from the OAP, petitioners argue that the Rule 4(c) report filed by respondent in *Poling* is binding on respondent in their case. *Id.* at 4. There is no evidence that this assertion is correct. Petitioners also argue that the doctrine of collateral estoppel is inapplicable here because petitioners were parties to the OAP at the time the *Poling* report was filed. *Id.* at 5. Nevertheless, petitioners argue, respondent should be unable to “relitigate an issue resolved within the Omnibus Cases as it applies to a former omnibus participant,” *id.* at 7, and essentially seek to invoke collateral estoppel against respondent as an alternative theory.

Petitioners renewed their motion in their post hearing brief⁶⁹ and again on June 17, 2014. See Motion to Renew Petitioners’ Motion to Compel Respondent’s Admission of the Medical Theory Upon Which Petitioners Rely, filed Jun. 17, 2014 (ECF No. 303). Respondent reiterated her objections to the invocation of estoppel. See Respondent’s Response to Petitioners’ Motions, filed Jul. 7, 2014 (ECF No. 308). The matter has remained pending.

b. Legal Standards and Analysis.

(1) Estoppel.

Estoppel is a common law doctrine that sometimes functions to prevent a party in one lawsuit from taking a contrary position or relitigating issues in a subsequent lawsuit. There are two discrete forms of estoppel—judicial and collateral. Judicial estoppel is used to prevent a party from making an argument in a legal proceeding that is inconsistent with an argument that same party took in a previous proceeding. *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001); see also *Pegram v. Herdrich*, 530 U.S. 211, 277, n.8 (2000). Under the doctrine of judicial estoppel, “where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him.” *Davis v. Wakelee*, 156 U.S. 680, 689 (1895). In essence, a party to litigation may not use an inconsistent position to seek an advantage when doing so would require the party to rely upon an incompatible theory. Judicial estoppel

⁶⁹ See Pet. Post-Hearing Memo, filed May 5, 2014, at 115-117 (ECF 297).

protects the integrity of the judicial process by “prohibiting parties from deliberately changing positions according to the exigencies of the moment.” *New Hampshire*, 532 U.S. at 750 (internal citation omitted). “Because the rule is intended to prevent improper use of judicial machinery, judicial estoppel is an equitable doctrine invoked by a court at its discretion.” *Id.*

As a threshold matter, judicial estoppel requires a final decision on the merits. It therefore does not apply if a party settled the claim in which it allegedly held a contrary or inconsistent position. *Moreland Corp. v. United States*, 76 Fed. Cl. 268, 294 (2007); see also *Vernacchio*, 2015 WL 1396357, at *5. Assuming that this basic requirement is met, courts then consider whether the invocation of judicial estoppel is appropriate.

In order to use the doctrine of judicial estoppel against an opposing party, a litigant must first satisfy three requirements. First, courts determine whether one party’s position is “clearly inconsistent” with its previous position. Second, courts consider whether a party’s later inconsistent position could pose a threat to judicial integrity. (Courts avoid accepting inconsistent positions in a later proceeding if doing so would “create the perception that either the first or the second court was misled.” *Moreland*, 76 Fed. Cl. at 294 (quoting *Cuyahoga Metropolitan Housing Authority v. U.S.*, 65 Fed. Cl. 534, 556 (2005)). Third, courts consider “whether the party seeking to assert an inconsistent position would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped.” *Id.*

Collateral estoppel, also known as issue preclusion, prevents a party from relitigating an issue that has already been decided. The doctrine provides that “a judgment on the merits in the first suit precludes relitigation in a second suit of issues actually litigated and determined in the first suit.” *Innovad Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1334 (Fed. Cir. 2001). Essentially, if a court has “decided an issue of fact or law necessary to its judgment, that decision may preclude relitigation of the issue in a suit on a different cause of action involving a party to the first case.” *San Remo Hotel, L.P. v. City and County of San Francisco, Cal.*, 545 U.S. 323, 336 n.16 (2005) (quoting *Allen v. McCurry*, 499 U.S. 90, 95 (1980)). As with judicial estoppel, in order to invoke collateral estoppel, a court must have issued a final decision on the merits of a case.

Although there are several ways a party can use collateral estoppel, the one most relevant to petitioners’ argument is offensive non-mutual collateral estoppel, whereby a new plaintiff in a later lawsuit attempts to assert a final judgment on a particular issue against the defendant from an earlier lawsuit. In such cases, courts employ the *Parklane Hosiery* test to determine whether the invocation of collateral estoppel is appropriate. Courts ask if the party trying to assert collateral estoppel could have intervened in the earlier suit; whether the defendant had incentive to litigate the first action; whether there are multiple prior inconsistent judgments; and whether there are any procedural opportunities available to the defendant in the second suit that were unavailable in the first suit. *Parklane Hosiery Co., Inc. v. Shore*, 439 U.S. 322 (1979). Very importantly, the doctrine of offensive non-mutual collateral estoppel generally does not apply to the federal government. *United States v. Mendoza*, 464 U.S. 154 (1984).

(2) Inapplicability of Collateral Estoppel to the Vaccine Program.

Collateral estoppel is never appropriate in Vaccine Act cases. In *Mendoza*, the Supreme Court held that non-mutual offensive collateral estoppel cannot be applied against the federal government. *Mendoza*, 464 U.S. at 160. The United States is inherently different than a private litigant due to the geographic scope and multiplicity of its litigation. *Id.* Furthermore, government litigation frequently addresses legal questions of substantial importance, and therefore allowing the United States to be subject to estoppel would “thwart the development of important questions of law.” *Id.*

The bar on the application of collateral estoppel against the United States includes Vaccine Program cases, despite petitioners’ policy arguments to the contrary. Under Section 12(b)(1) of the Act, the Secretary of the Department of Health and Human Services, a federal entity, is officially designated to defend against a petitioner’s claim. 42 U.S.C. § 300aa-12(b)(1). Numerous vaccine cases have affirmed the inapplicability of the collateral estoppel doctrine in this context. *See, e.g., Bast v. Sec’y, HHS*, 117 Fed. Cl. 104, 124 n. 18, *appeal dismissed sub nom., M.S.B. ex rel. Bast v. Sec’y, HHS*, 579 F. App’x 1001 (Fed. Cir. 2014); *Stewart v. Sec’y, HHS*, No. 06-777V, 2011 WL 2680580, at *2 (Fed. Cl. Spec. Mstr. June 15, 2011); *Sharkey v. Sec’y, HHS*, No. 99-669V, 2010 WL 5507915, at *1 (Fed. Cl. Spec. Mstr. Dec. 10, 2010).

While there are some exceptions to the bar against collaterally estopping the federal government,⁷⁰ petitioners are unable to demonstrate that such circumstances exist in their case. Claims authorized by the Vaccine Act are very fact-specific. “A special master’s acceptance of a theory in one case does not require him or her to accept the theory in subsequent cases involving similar facts or the same vaccine. Rather, a different evidentiary record can lead to different outcomes.” *Rickett v. Sec’y, HHS*, 468 Fed. Appx. 952, 959 (Fed. Cir. 2011). Given the varied nature of Vaccine Act cases, and the ever-evolving medical and scientific evidence that informs their resolution, collateral estoppel can never be appropriate. To determine otherwise would “thwart the development of important questions of law by freezing the first final decision.” *Mendoza*, 464 U.S. at 160. Thus, petitioners are unable to use the doctrine of non-mutual offensive collateral estoppel against respondent in this case.

(3) Inapplicability of Judicial Estoppel to this Case.

Although it is abundantly clear that petitioners cannot invoke collateral estoppel against respondent in this or any other case, I am unaware of any similar bar against the application of judicial estoppel in Vaccine Act cases. *See Vernacchio*, 2015 WL

⁷⁰ For instance, the bar may not apply where the public policy considerations that favor suspension of collateral estoppel are not present. *See, e.g., N.L.R.B. v. Donna-Lee Sportswear Co., Inc.*, 836 F.2d 31 (1st Cir. 1987) (holding that the private interest of the parties predominates so the public policy considerations were not valid). Similarly, the doctrine has been applied against the United States where it was only a nominal party with no demonstrated direct interest in the subject matter of the suit. *Westerchil Const. Co., Inc. v. United States*, 16 Cl. Ct. 727, 732-33 (1989).

1396357, at *5) (remarking that petitioners' judicial "estoppel argument does not appear to have been advanced in any Vaccine Program cases before."). Nevertheless, for reasons explained below, petitioners' motion for judicial estoppel fails.

However, there are at least four reasons against applying judicial estoppel against respondent in this case. First, and most importantly, judicial estoppel does not apply when a claim has been settled. Petitioners seek to treat the statements contained in respondent's *Poling* Rule 4(c) report as a global concession (with respect to all subsequent cases involving alleged preexisting mitochondrial disorders) of the first prong of *Althen*. But petitioners have somehow missed an essential fact. *Poling* was settled, not adjudicated, and "judicial estoppel does not apply where a party settles the claim in which it is alleged to have made an inconsistent statement." *Moreland*, 76 Fed. Cl. at 295; see also *United States v. International Bldg. Co.*, 345 U.S. 502, 506 (1953) (holding that a settlement is not an adjudication on the merits and that applying judicial estoppel in such a case "would serve an unjust cause: it would become a device by which a decision not shown to be on the merits would forever foreclose inquiry into the merits.").

Second, petitioners have failed to satisfy the three requirements for the invocation of judicial estoppel. Respondent's position in this case is not "clearly inconsistent" with her position in *Poling*. In *Poling*, respondent's position was that the child had sustained a Table injury within the timeframe established for both the MMR and DTaP vaccinations, and thus presumptively should be compensated. Here, there is no allegation that A.K. suffered a Table injury within the requisite time period. I also note that the allegedly causal vaccine, influenza, was not associated with a Table injury—nor was it even on the Vaccine Injury Table as a vaccine covered by the Program—at the time that this claim was filed. Lacking an inconsistent position, there can be no threat to judicial integrity.

Allowing respondent to argue against entitlement to compensation in A.K.'s case in no way "create[s] the perception that either the first or the second court was misled." *Moreland*, 76 Fed. Cl. at 294 (quoting *Cuyahoga*, 65 Fed. Cl. 556). Moreover, respondent derives no unfair advantage and imposes no unfair detriment on the opposing party if not estopped. *Id.* Indeed, declining to apply judicial estoppel against respondent in this case imposes no additional burden on petitioners; in order to establish entitlement to compensation, they must either demonstrate that A.K. suffered a Table injury or provide preponderant evidence that A.K.'s influenza vaccinations actually caused his condition, using the framework established by *Althen* and its progeny. Petitioners here are in precisely the same situation as all other Vaccine Act claimants. Declining to provide them with special treatment does not constitute an unfair burden.

Third, decisions issued by special masters and judges of the Court of Federal Claims constitute persuasive, not binding, authority. *Guillory v. Sec'y, HHS*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *Hanlon v. Sec'y, HHS*, 40 Fed. Cl. 625, 630 (1998), *aff'd*, 191 F.3d 13444 (Fed. Cir. 1999). "Special masters are

neither bound by their own decisions nor by cases from the Court of Federal Claims, except, of course, in the same case on remand.” *Id.* at 630. This is especially true in cases like these which involve different vaccines (in the instant case, one without any associated Table injury), a different clinical presentation, and different timing. Thus, even if the causation theories in two cases are identical, another special master’s determination about a petitioner’s causation theory does not compel me to reach an identical conclusion.

Fourth and finally, a concession by respondent in one case does not constitute a concession in another. Science and medicine are not immutable, and as the SCN1A (Dravet syndrome) cases demonstrate,⁷¹ what was once viewed as a Table encephalopathy is now known to be a genetic condition that cannot be compensated. Evidence filed in one case may not be filed in another case. For example, a concession that the measles vaccine can cause an encephalopathy occurring within 5 to 15 days of a vaccination is not a concession that it can do so at times shorter or longer. *Shyface v. Sec’y, HHS*, 165 F.3d 1344, 1351 (Fed. Cir. 1999) (quoting the legislative history of the Vaccine Act asserting that a similarity to conditions or time periods in the Table would not be sufficient to demonstrate vaccine causation). Thus, even if judicial estoppel could be invoked against respondent based on the settling of the *Poling* case, it would be impossible to do so here, where petitioners allege an entirely different vaccination significantly aggravated their son’s condition.

c. Estoppel Motion Rejected.

Neither judicial nor collateral estoppel is appropriate in this case, and so petitioners cannot compel respondent to admit their causation theory. Collateral estoppel can never be appropriate in Vaccine Act cases. Judicial estoppel on the basis of the *Poling* Rule 4(c) Report is inappropriate because the *Poling* case was not adjudicated, because petitioners failed to satisfy the three requirements for the invocation of the doctrine, because the decision of one special master is not binding on other special masters, and because the vaccines and injuries alleged in the two cases in question are completely different. **For these reasons, petitioners’ motion for estoppel is DENIED.**

7. Motions Pertaining to *Poling*.

Because respondent affirmatively used the *Poling* Rule 4 report, Pet. Ex. 57, in this case, it is admitted. The admission of Dr. Zimmerman’s expert opinion letter is addressed in subsection II., below.

⁷¹ See *Barclay v. Sec’y, HHS*, 122 Fed. Cl. 189 (2015).

C. Motions to File Exhibits Out of Time.

1. Background.

Prior to the entitlement hearing in this case, I set a deadline of March 22, 2013, for the filing of medical literature. Order, issued Feb. 21, 2013 (ECF No. 199). In conjunction with this prehearing order, I included letters for each expert identified as testifying, stressing the importance of providing supporting medical literature to counsel for filing prior to the entitlement hearing in this case. See attachments to Prehearing order, ECF No. 199.

On the day the medical literature was due, petitioners' requested a four day extension, indicating that they would be filing over 100 additional medical journal articles. ECF No. 210. I granted their request, but warned them that I would not consider additional literature filed after that date, absent a compelling reason. ECF No. 214. On March 26, 2013, petitioners filed over 100 medical journal articles. Less than 10% of these articles were actually discussed during the testimony or otherwise relied upon at the hearing.

On April 24, 2013, while the hearing was on-going, petitioners requested leave to file Pet. Ex. 240, a recently published medical journal article. I granted their request. This article was discussed extensively during the hearing. Four days later, petitioners requested to file another newly published journal article, Pet. Ex. 241. I likewise granted this request.

Also during the hearing, petitioners provided copies of the slides that Dr. Deth would be using to illustrate and supplement his testimony. See Pet. Exs. 239-40. The slides referenced 25 medical journal articles that had not been filed in the case. I therefore ordered petitioners to file all the journal articles thus referenced. When they initially did so on May 31, 2013, they did not assign exhibit numbers to any of the articles. Rather, they listed them by the slide number on which they appeared, referring to page numbers of Pet. Ex. 239. I required petitioners to assign exhibit numbers to each slide and to file an updated exhibit list. Order, issued Jun. 6, 2013 (ECF No. 270). That exhibit list was filed on June 25, 2013 (ECF No. 271). Because the exhibits were not re-filed, a chart reflecting the crosswalk between the articles and exhibit number is set forth below.

ECF No.	Ex. # in filing	Redesignated Ex. #	Article Author and Short Title
260	Pet. Ex. 239, Slides 15, 44	Pet. Ex. 242	Numata, DNA Methylation Signatures
260	Pet. Ex. 239, Slides 16, 45	Pet. Ex. 243	Colantuoni, Temporal dynamics
260	Pet. Ex. 239, Slide 19	Pet. Ex. 244	Kiley, Exploiting Thiol Modifications
260	Pet. Ex. 239, Slide 22	Pet. Ex. 245	Kil, Regulation of Mitochondrial NADP+
260	Pet. Ex. 239, Slide 23	Pet. Ex. 246	Hurd, Complex I within Heart Mitochondria
260	Pet. Ex. 239, Slide 25	Pet. Ex. 247	Cy, Redox Basis of Epigenetic Modifications
260	Pet. Ex. 239, Slide 27	Pet. Ex. 248	Prozorovski, Sirt1
260	Pet. Ex. 239, Slide 35	Pet. Ex. 249	Castagna, Cerebrospinal fluid SAME
260	Pet. Ex. 239, Slide 35	Pet Ex. 250	Sun, Imaging of Glutathione Levels
260	Pet. Ex. 239, Slide 47	Pet. Ex. 251	Csibra, Gamma Oscillations in Infant Brain
261	Pet. Ex. 239, Slide 51	Pet. Ex. 252	Andersson, Dopamine D4 Receptor Activation
261	Pet. Ex. 239, Slide 51	Pet. Ex. 253	Law, Neuregulin signaling in schizophrenia
261	Pet. Ex. 239, Slide 53	Pet. Ex. 254	Just, Cortical activation high-functioning ASD
261	Pet. Ex. 239, Slide 54	Pet. Ex. 255	Sun, Impaired Gamma-Band Activity in ASD
261	Pet. Ex. 239, Slide 57	Pet. Ex. 256	Frustaci, Oxidative stress-related biomarkers
261	Pet. Ex. 239, Slide 67	Pet. Ex. 257	Chez, Elevation of TNF α in CSF in ASD
261	Pet. Ex. 239, Slide 67	Pet. Ex. 258	Li, Elevated Immune Response in ASD Brains
261	Pet. Ex. 239, Slide 69	Pet. Ex. 259	Whitney, Inflammation in neurogenesis
261	Pet. Ex. 239, Slide 77	Pet. Ex. 260	Peake, Action of Anti-TNF α in Crohns
261	Pet. Ex. 239, Slide 78	Pet. Ex. 261	Graf, Gliadin Peptides in Celiac Disease
262	Pet. Ex. 239 Slide 84	Pet. Ex. 262	Yan, Reg T Cells & Glutathione Metabolism
262	Pet. Ex. 239 Slide 87	Pet. Ex. 263	Khan, Translocation of biopersistent particles
262	Pet. Ex. 239, Slide 89	Pet. Ex. 264	Schroder, NLRP3 Inflammasome:
262	Pet. Ex. 239, Slide 91	Pet. Ex. 265	Capuron, Immune System to Brain Signaling:
262	Pet. Ex. 239, Slide 92	Pet. Ex. 266	D'Mello, Cerebral Microglia Recruit Monocytes

I allowed respondent's expert, Dr. Johnson, to address petitioners' late-filed medical literature. Post-Hearing Order, issued Sept. 9, 2013 (ECF No. 278). Then, in an effort to ensure that both parties had an adequate opportunity to perfect their cases, I allowed petitioners until October 9, 2013 to make any additional evidentiary filings they desired; and gave respondent until November 8, 2013 to do the same. I indicated my intent to close the record at that point, after which I would set a deadline for post-hearing briefs. *Id.* Both parties made substantial use of the opportunity for additional evidentiary filings. On November 15, 2013, I informed the parties that the evidentiary record in this case was complete and ordered them to file post hearing briefs. Post Hearing Order, issued Nov. 15, 2013 (ECF No. 282).

In various motions since, petitioners have requested that I admit additional medical journal articles. Some have had only the most tenuous of relationships to the matters presented at hearing. Others were available long before the record closed, but were just "discovered" by petitioners. Most were cumulative of the matters addressed in the volumes of medical literature already filed in this case, and only about 130 of the approximately 280 medical journal or similar articles petitioners were filed were actually mentioned in expert reports or discussed in testimony. Petitioners' difficulty in keeping track of exhibit numbers they have previously used contributes to the problems posed

by their late filings.⁷² See, e.g., Motion for Leave to File Exhibit 240, filed Jan. 14, 2014 (ECF No. 284) (re-using an exhibit number and refiled on Jan. 16, 2014 as Pet. Ex. 270); Motion for Leave to File Exhibits 240,⁷³ 271, 272, 273, 274, 275, 276, 278, 280, 281, and 282, filed Jun. 17, 2014 (ECF No. 303); Supplemental Motion for Leave to File Exhibit 277 and 279, filed Jun. 26, 2014 (ECF No. 306). Petitioners also skipped over numbers 267 and 268, so their proposed exhibit numbers jump from 266 to 269.

Many of the motions to admit this late filed medical literature have remained pending. I rule on those motions now.

2. Legal Standards and Analysis.

When deciding whether new evidence justifies re-opening the record, special masters have devised a four-factor test: “(1) the nature of the proffered new evidence; (2) the prejudice to the parties; (3) the length of the delay; and (4) the reason for the delay.” *Vant Erve v. Sec’y, HHS*, 39 Fed. Cl. 607, 612 (Fed. Cl. 1997), *cited favorably by Plavin v. Sec’y, HHS*, 40 Fed. Cl. 609 (1998). Of these inquiries, the “paramount test is the nature of the proffered new evidence.” *Id.* at 612. Special masters must consider “the extent to which the new evidence is both relevant and affective of the outcome.” *Id.* In instances where the proffered evidence “is of marginal relevance and impact,” the moving party faces a significantly higher burden “with respect to the influence of the remaining factors.” *Id.* at 612 (citing *Horner v. Sec’y, HHS*, 35 Fed. Cl. 23, 27 (1996)). But the inverse is also true—if the proffered evidence is “highly relevant and clearly outcome determinative...the importance of the remaining factors diminishes.” *Plavin*, 40 Fed. Cl. at 612 (citing *Kaminski v. Sec’y, HHS*, 39 Fed. Cl. 253 (1997)).

Petitioners have not persuaded me that most of their new evidence justifies re-opening the record. First, the additional evidence is cumulative in nature; the record already contains many articles about mitochondrial disorders and brain development, oxidative stress, and various biochemical abnormalities seen in ASD. Second, given the number of articles already filed addressing these same issues, they are in no way prejudiced by my declining to re-open the record months after I declared it closed. And finally, several of the proffered articles were published well before the record was closed. Petitioners’ lack of diligence in researching and identifying articles in a timely fashion is not a sufficient reason to accept these articles into the record. Petitioners could have filed them into the record long before I announced that the record was closed. Petitioners’ failure to file them in a timely manner does not constitute a justification to re-open the record.

⁷² This remarkable level of disorganization is not uncommon in Mr. McHugh’s office. See *Rodriguez v. Sec’y, HHS*, No. 06-559V, 2009 WL 2568468, at *23 (Fed. Cl. Spec. Mstr. Jul. 27, 2009) (where I deducted several hundred dollars from an attorney’s fees decision “based on Mr. McHugh’s poor performance in preparing and filing the exhibits in this case.”)

⁷³ Apparently petitioners’ counsel forgot that he had redesignated the Rose article, which reused Pet. Ex. 240 (previously assigned to the Wong article), as Pet. Ex. 270.

3. Granting in Part and Denying in Part Motions to File Late Exhibits.

Given that I had to read each of the journal articles to see if they contained the smoking gun for which petitioners have been searching, it is simpler at this point to admit all of the proffered exhibits, with the exception of Pet. Ex. 277, which is addressed separately below. This is in keeping with the approach taken to other evidentiary issues in Vaccine Act cases. It is rare, for example, for a *Daubert* motion to be granted, even though the special master may ultimately chose to reject an expert's opinion entirely in reaching a decision. Unfortunately, it rewards petitioners' disregard of my orders, which were designed to allow this case to be resolved as fairly and expeditiously as possible. I also note that medical literature not discussed by an expert is often of little utility, even to a special master well-versed in the subject matter of the article.

I stress that none of these exhibits has had any impact on the causation decision rendered in this case, but the time and effort required to apply the tests used to determine whether they should be admitted would simply delay resolution of this case, which has been pending for 12 years. As noted above, these late filed exhibits were largely cumulative of other previously filed documents.⁷⁴

Petitioners' Ex. 277 was discussed extensively in Section II.B, above (in conjunction with the motions to subpoena Dr. Zimmerman and for application of judicial estoppel to this case). This letter constitutes a matter submitted by a party in another Vaccine Act case and, as such, it falls under the protection of § 12(d)(4)(A). As petitioners have not also filed the express written consent of the party submitting it, I cannot admit it into the record of this case. I will not consider it as substantive evidence in this case. **The portions of this ruling that discuss the substance of the letter will be redacted from public view.**

Petitioners' motions to file what had previously been identified as exhibits 238, 238A, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 269, 270, 271, 272, 273 274,⁷⁵ 275, 276, 278, 279, 280, 281, and 282 (chart filed June 16, 2014, at ECF No. 302), 274A (Funding Opportunity Announcement, filed June 17, 2014, at ECF No. 303),⁷⁶ are GRANTED. Petitioners' motion to file Pet. Ex. 277 is DENIED.

⁷⁴ In fact, most of the articles seem to relate to Dr. Deth's presentation, which, as noted in the causation decision, already cited many, many articles that were only tangentially related to his opinion. After reviewing these late-filed articles, I concluded that petitioners' flurry of late filings, relevant only at the broadest levels, have not cured the core deficiencies in their experts' theories.

⁷⁵ Petitioners assigned exhibit number 274 to two exhibits. I designate the later-filed exhibit as "274A".

⁷⁶ I note that respondent's objections to the relevance of this document are well-founded. Resp. Response to Petitioners' Motions, filed July 7, 2014, at 1-4 (ECF No. 308).

D. Motion to Exclude OAP Evidence.

1. Background.

By filing their short-form petition in 2003, petitioners in this case joined the OAP. See Section I(A), *supra*. After first agreeing to be a test case for Theory 2, they withdrew in April of 2008, both as a test case and from the OAP. See Motion to Withdraw Claim as a Test Case, April 10, 2008 (ECF No. 40). While a part of the OAP and while still a test case, respondent filed medical literature pertaining to the use of video evidence in autism diagnosis and research (Res. Exs. A, C-E); the timing and nature of early autism symptoms recognized by parents (Res. Ex. B); and regression in autism (Res. Ex. F). These articles were filed primarily due to a dispute between the parties about my order to petitioners to file video footage of A.K., with respondent asserting the validity of the use of videos in diagnosis of ASD.

On February 25, 2008, also while this case was still designated as a test case, respondent filed reports and CVs from her Theory 2 experts on general causation. See Res. Exs. G-HH. (ECF No. 27). Two of the reports and accompanying CVs were later withdrawn from the OAP Theory 2 cases, and from this case in particular, long after petitioners had withdrawn as a Theory 2 test case. Of the remaining expert reports, two involved experts who also testified in this case (Drs. Johnson and Jones) (Res. Exs. Q and S, respectively). Another, Dr. Manuel Casanova, was the author of a medical journal article that gave rise to Dr. Shafrir's "triple hit" hypothesis. Still others, Drs. Fombonne, Goodman, Lord, and Rutter, provided considerable information about autism, regression in autism, and the epidemiology, matters highly relevant to petitioners' arguments about A.K.'s purported regression, the onset of his symptoms, the clinical course of ASD, and whether there truly exists the "autism epidemic" about which Dr. Shafrir testified in this case. The expert reports of Drs. Rodier and Kemper addressed the prenatal origins of ASD, a matter highly relevant to evaluation of Dr. Shafrir's "triple hit" hypothesis, in which he asserted that events occurring in the second or third year of life could be environmental triggers for regression and ASD. The report of Dr. Rust, a pediatric neurologist and ASD specialist, on general causation was filed on March 14, 2000, as Res. Ex. II. ECF No. 32. A case-specific expert report from Dr. Rust was filed a few days later as Res. Ex. KK. ECF No. 35. Respondent's Master List of journal articles was filed on March 21, 2008, with the actual articles filed on a CD. ECF No. 36.

Petitioners filed expert their OAP Theory 2 expert reports on March 20, 2008, including a report by Dr. Deth, one of their experts at the hearing in this case. ECF No. 34. Petitioners have never moved to withdraw these three reports, although they did request to withdraw Dr. Mumper's report, filed earlier, and I granted that request.

In April 2008, petitioners withdrew as a test case, stating that they had decided that A.K.'s case specific circumstances indicated that other causes might have contributed to his ASD symptoms. However they noted that they might still rely to some degree on the thimerosal causation theory: "By withdrawing his claim as a test case

petitioner [sic] does not mean to imply any waiver whatsoever of the claim that TCVs contributed to his autistic symptoms; instead, petitioner [sic] withdraws his claim as a test case because he seeks an opportunity to develop and present evidence of additional and alternative causative factors.” Motion to Withdraw Claim as a Test Case, filed Apr. 10, 2008; ECF No. 40 at 1.

The only additional evidence from the OAP filed into the record of this case were transcripts of some of the testimony, including cross examination in the OAP test cases from several of the experts whose reports were filed earlier into the record of this case. See Res. Ex. LL, filed Oct. 11, 2011. ECF No. 145. These transcript excerpts were filed in response to my order of July 12, 2011, for respondent to designate any OAP hearing evidence on which she intended to rely in this case.

2. Petitioners’ Motion to Exclude OAP Evidence.

Petitioners’ April 2013 Motions *in Limine* included a motion to exclude evidence, expert reports, medical literature, and witness testimony from the OAP. *Id.* at 20-25. ECF No. 227. Petitioners correctly asserted that they were permitted to withdraw from the OAP when I granted their motion to do so on April 15, 2008. *Id.* at 21. Further, because their theory—that A.K.’s vaccination significantly aggravated an underlying mitochondrial disorder—was not explored in the OAP, they argued that OAP evidence should be excluded from their case. *Id.* at 22.

Petitioners relied on *Paluck ex rel. Paluck v. Sec’y, HHS*, 104 Fed. Cl. 457 (2012), a case in which the special master relied in part on evidence from the OAP to decide a case which had not been part of the OAP. In *Paluck*, Judge Lettow expressed his concern about this, commenting that the special master could not use his authority “in a way that deprives a party of procedural rights provided by the Vaccine Act and the Vaccine Rules.” *Paluck*, 104 Fed. Cl. at 484 (quoting *Simanski v. Sec’y, HHS*, 671 F.3d 1368, 1385 (Fed. Cir. 2012)).

Petitioners also contended that using OAP evidence in their case would violate the Sixth Amendment’s confrontation clause. Motions *in Limine* at 24, n.13 (ECF No. 227).⁷⁷

Respondent argued that petitioners voluntarily “availed themselves of the OAP process,” which included the admission of OAP evidence into their case. Res. Response at 4 (ECF No. 258). According to respondent, petitioners’ claim that the OAP evidence was not relevant to their new theory does not constitute a basis to exclude the evidence, because under the less stringent procedural rules and evidentiary practices applied in the Vaccine Program, relevance affects the evidence’s weight, not its

⁷⁷ This argument is patently absurd. By its terms, the Confrontation Clause of the Sixth Amendment to the U.S. Constitution applies only to criminal cases. The Vaccine Act does not even require hearings or extend the right to cross-examine witnesses. § 12(d)(2)(D). I recognize that the issues in this case are very emotionally charged for petitioners, but ridiculous arguments such as this one detract attention from whatever merit their other arguments may have.

admissibility. See *Moberly v. Sec’y, HHS*, 592 F.3d 1315, 1325 (Fed. Cir. 2010); *Munn v. Sec’y, HHS*, 970 F.2d 863, 871 (Fed. Cir. 1992).

In their Reply, petitioners renewed their motion to exclude OAP evidence, again arguing that it is irrelevant. Pet. Reply at 13 (ECF No. 259). Petitioners called much of the proffered testimony “irrelevant and outdated.” *Id.* Further, since petitioners have not claimed that thimerosal caused A.K.’s injury, they argued that all OAP evidence regarding thimerosal or mercury toxicity should be struck from the record. *Id.* at 14. They went on to claim that “any neurologist or pediatrician who testified as an expert in the field in 2008 that [an ASD] epidemic did not exist is not credible,” and thus the testimony of Drs. Eric Fombonne and Max Wiznitzer’s and their expert opinions should be struck from the record.⁷⁸ *Id.* at 15-17.

Petitioners also claimed that the Vaccine Act “requires that any condition asserted in a vaccine case be supported in the medical record” and therefore that any testimony that A.K. exhibited symptoms of ASD that was not supported in the medical records was irrelevant. Motions *in Limine* at 16. They requested that the testimony of Dr. Bennett Leventhal be struck because he discussed tests that were conducted on a child in the OAP test case, not A.K.⁷⁹ *Id.* at 18.

3. Legal Standards.

Special masters have “virtually unlimited” power to “inquire into matters relevant to causation.” *Snyder*, 2009 WL 332044, at *2; *Whitecotton v. Sec’y, HHS*, 81 F.3d 1099, 1108 (Fed. Cir. 1996). Congress “contemplated that the special masters would develop expertise in the complex medical and scientific issues involved in actual causation claims and would then apply this expertise to the resolution of other cases.” *Snyder*, 2009 WL 332044, at *2. This policy favoring broad inclusion of evidence is echoed in the Vaccine Rules, which instruct special masters that they are “not...bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.” Vaccine Rule 8(b)(1).

4. Analysis.

Unlike *Paluck*, this is not a case where evidence was imported by the special master from the OAP for use in a case that was not a part of the OAP. The evidence

⁷⁸ That petitioners and their expert, Dr. Shafir, reject the epidemiological evidence proffered in the test cases is clear. That disagreement does not give them the authority to control the admissibility of such evidence. Doctor Shafir’s opinions on the mainstream approach to ASD’s diagnosis, treatment, and causes, are discussed at some length in the causation decision in this case. Doctor Shafir’s opinions that there is an autism epidemic caused by postnatal environmental factors such as vaccines is rebutted by the scientific evidence contained in the reports and testimony of these ASD experts from 2008, as well as the testimony and reports specific to this case.

⁷⁹ I have not relied in any way on Dr. Leventhal’s testimony contained in Res. Ex. LL, but “striking” it is unnecessary.

petitioners seek to exclude, on the dubious basis that all of the evidence in the OAP is somehow irrelevant to their case, was actually filed into the evidentiary record in this case. Regardless of their source, the expert reports, transcripts, and medical journal articles filed are evidence in this case. Petitioners were well aware of what the evidentiary record included; they cannot claim surprise or a lack of opportunity to respond to this evidence.

The timing for their motion to exclude this evidence is highly suggestive of gamesmanship. The motion was filed on April 8, 2013. ECF No. 227. I had earlier extended the deadlines for all pre-evidentiary findings (at petitioners' request) with respondent's deadline extended to April 1, 2013. Thus, the exclusion of evidence would effectively preclude respondent filing similar evidence from another source. And, if I delayed the case to allow them to obtain additional evidence, respondent could simply file new reports from the same experts or even the same reports again. Neither scenario would have worked to petitioners' advantage.

The OAP evidence not specifically filed into the docket of this case was made publically available in the OAP test case dockets. The transcripts of the hearing testimony were likewise made publically available. While, due to copyright restrictions, the medical and scientific journal articles themselves were not available on the OAP docket (<http://www.cofc.uscourts.gov/docket-omnibus-autism-proceeding>), the master lists of these articles were publically available, and respondent's Master List, including all of the medical journal articles on that list, was actually filed into the record of this case.⁸⁰ Finally, and most significantly, the detailed and comprehensive decisions of the special masters were drafted with the purpose of setting forth the available and relevant evidence for the purpose of not only resolving the specific test cases, but to create a body of evidence that would aid in resolving the remaining cases.⁸¹ Nevertheless, with the exception of occasional citations to the test case decisions, this evidence was not used to resolve this case.⁸² This obviates any need to determine whether OAP

⁸⁰ The causation decision in this case does not rely on any medical journal article not filed into the record of this case.

⁸¹ Although the parties were able to supplement OAP evidence with additional materials, there is nothing in Autism General Order #1 to suggest that OAP evidence should be excluded from subsequent cases. Had the OAP produced a ruling on general causation issues favorable to petitioners, they would have been "ordered to demonstrate that [their] case qualifies for compensation under the general ruling." Autism General Order #1 at 6-7. Because the OAP general causation rulings were unfavorable to petitioners' case, they received "the opportunity to introduce additional supportive case-specific evidence." *Id.*

⁸² There exists one limited exception, which involves Dr. Deth. When petitioners indicated that they intended to use Dr. Deth as one of their experts in this case, I cautioned them that I did not intend to permit the re-litigation of the theories he had presented in the Theory 2 OAP test cases, absent new evidence suggesting that the prior resolution was incorrect. I noted that the evidence he presented in the Theory 2 test cases was not well-received, and urged them to look at the test case decisions before retaining Dr. Deth. Doctor Deth's expert report in the OAP was already a part of the record in this case. When he testified in this case, I recognized that many of the PowerPoint slides he was using were the same slides he had used during his earlier testimony, to include an illustration from a 1958 medical journal article purporting to show evidence for a "block" in the transsulfuration cycle in the human brain. Thus, I have used my own knowledge of Dr. Deth's testimony in both the test cases and A.K.'s case, as

evidence can be used in other cases that were once a part of the OAP.⁸³

Perhaps the most disturbing aspect of petitioners' request to exclude is that granting it would, in effect, give petitioners control over the source of any evidence respondent might file. Petitioners were as free as respondent to file information from the OAP—and, through the testimony of Dr. Deth, they did so.

Although petitioners claimed that they were not relying on a mercury theory of causation any longer (a matter not clear until they filed their second amended petition and which they had expressly reserved the right to do in withdrawing from the OAP), Dr. Deth talked about mercury on his slide presentation and during his testimony at the hearing in this case. Additionally, A.K.'s medical records from Dr. Boris reflected that he was chelated to remove mercury and other "toxic metals" from his body, and reflected Dr. Boris's diagnoses related to these matters. While it is undoubtedly true that some of the matters filed by respondent from the OAP were not precisely relevant to A.K.'s case, the advantage of a bench trial is that the special master may simply disregard irrelevant matters after the hearing and post-hearing processes are complete without having to determine, in advance of hearing the testimony, what is relevant and what is not.

Generally, "in omnibus proceedings, the parties consent to import evidence from the 'test case' into other individual cases." *Snyder*, 2009 WL 332044, at *2 n.8. Here, petitioners voluntarily agreed to join the OAP. While their case was part of it, they benefitted from the coordinated litigation efforts of the PSC and the development of new scientific studies. As part of their agreement, they consented to the inclusion of OAP evidence in their case. The fact that petitioners later withdrew from the OAP is of no consequence, because the evidence to which they object is already part of the record in their case.

well as both of his expert reports in assessing to what degree such testimony overlapped and where it was distinct. I note that I was concerned enough about the lack of support for Dr. Deth's opinions, his practice of cherry-picking data from other researchers, and his misstatements about the findings of other researchers, and his tendency to offer opinions on matters in which he was not qualified to opine in the OAP to decline to award interim fees and costs for Dr. Deth's expenses when I made the first interim fees award in this case.

⁸³ In one sense, the OAP ended when the PSC disbanded after the conclusion of the appellate proceedings in the test cases. See Autism Update, Jan. 12, 2011, available at <http://www.cofc.uscourts.gov/docket-omnibus-autism-proceeding> (noting the disbandment of the PSC). In another, based on the intent of the parties when it was created and the purposes behind its creation, all of the cases that were once a part of the OAP are affected by the evidence created in the test cases. As Autism General Order #1 indicates, at the time the OAP was created, petitioners acknowledged that there was insufficient evidence to prove vaccine causation of ASD, but averred that the evidence was obtainable through a discovery process. Thus, petitioners, including petitioners in the instant case, whose cases were subject to dismissal for lack of evidence of causation at the time they were filed achieved a lengthy period of delay. Petitioners in this case were the beneficiaries of that period of delay. It is highly unlikely that respondent would have entered into the agreement to create an omnibus proceeding, absent the understanding that the evidence would be available for use in other cases that were not only once a part of the OAP, but relied on some of the same theories that were presented in the OAP. This is particularly true in this case, given Dr. Deth's opinions, testimony, and supporting slides and literature.

Petitioners have cited no authority that compels or persuades me to remove evidence that is already part of the record. Anything filed into the docket in A.K.'s case while it was part of the OAP that was not subsequently withdrawn on motion by one of the parties remains part of the record. This includes, *inter alia*, the reports and CVs from some 13 experts regarding general causation issues.

5. Ruling on Motion to Exclude Evidence.

All of the evidence filed into the record of this case not specifically excluded (by an earlier order or the granting of an earlier motion to withdraw it) remains a part of the evidentiary record. The Vaccine Rules favor broad inclusion, and “the probative value of the evidence or the credibility of the witnesses...are matters within the purview of the fact finder.” *Munn*, 970 F.2d at 871. To the extent that petitioners’ motion to exclude evidence refers to OAP evidence not in the record of this case, it is effectively moot. As noted above, the causation decision in this case does not rely on any medical literature not filed in this case. And, although the relationship between Dr. Deth’s testimony in the OAP and his testimony in the instant case is highly complex, I stress that discussion of Dr. Deth’s prior OAP opinion pertains to Dr. Deth’s *own* testimony in this case and my conclusions regarding Dr. Deth’s qualifications and reliability as an expert, and not as substantive evidence.⁸⁴

E. Substitution of Child Development Expert.

At a March 13, 2013 status conference, petitioners informed me that Dr. Megson, their pediatric development specialist, was ill and would be unable to participate in the hearing. They indicated that they were looking for another expert, but it would be unlikely that any new expert would be prepared to testify at a hearing six weeks hence. Petitioners suggested that another session of the causation hearing would be appropriate. Petitioners reiterated this history and their request in the Motions *in Limine*, ECF No 227, at 26-29.

I did not rule on petitioners’ request at the March 13, 2013 status conference, nor did I indicate that their request to obtain a new expert would not be granted. I did note that it had taken petitioners some time to find a pediatric development specialist willing to opine, and suggested that they attempt to find another. The need for a second

⁸⁴ Ultimately, the nature and significance of my citations to Dr. Deth’s prior OAP opinion are bound up in the substance of his testimony in the present case. Therefore, the extent of my reference to Dr. Deth’s OAP testimony and its implications are best understood in the context of the causation decision. These issues are addressed in greater detail therein. I do note, however, that although my discussion of Dr. Deth’s opinion in this case extensively addresses the similarities between Dr. Deth’s instant presentation and his previously rejected OAP presentation, that aspect of the discussion represents only a single part of the overall analysis. It is therefore worth noting that my ultimate conclusion regarding Dr. Deth’s opinion would remain the same with or without reference to the OAP. Furthermore, I do not rely on any materials that have not been filed in this case; nor do I discuss any fact or observation not published in my prior *Dwyer* decision. Petitioners were therefore fully on notice regarding every aspect of the final analysis.

session of the entitlement hearing to take the testimony of such a witness could be discussed once they found an expert. It was also possible that Dr. Megson might become available, although petitioners could not supply any information about Dr. Megson's prognosis for return to work.

At the April 9, 2013 status conference, we discussed the issue of a replacement expert. Audio Tr. 2:38-42 (petitioners reported that they intended to replace Dr. Megson with another unspecified expert, who would provide an expert report by June 1, 2013).

Post-hearing, petitioners reported that they had found another expert, and I set a deadline for filing that unidentified expert's report. ECF No. 257. In July 2013, petitioners reported that they would not be filing such a report and requested that Dr. Megson be allowed to testify via video in late summer or fall. ECF No. 272. Less than two weeks later, citing excessive costs,⁸⁵ petitioners indicated that they would rely only on Dr. Megson's report without the need for further testimony. Status Report, ECF No. 275.

This renders their motion to obtain a new expert, file that expert's report, and take the expert's testimony moot.⁸⁶

F. Motion to Strike Dr. Miller's Testimony.

1. Motion.

Doctor Judith Miller, a clinical psychologist specializing in the diagnosis of ASD, testified on behalf of respondent on April 25, 2013. Her qualifications to opine are set forth in some detail in the entitlement decision in this case. This was her first appearance as an expert witness in any court, including the Vaccine Program. Tr. 846.

Prior to her testimony, Dr. Miller reviewed A.K.'s medical records and home videos, but did not meet A.K. In summary, she opined that A.K. has autism, the signs of which were apparent by the time he was 14 months old. Additionally, she opined that the evidence does not support petitioners' claims that A.K. experienced a developmental regression. Tr. at 895-96, 916-19, 938-39. Her testimony was devastating to petitioners' theories of causation.

⁸⁵ Petitioners had not at that point requested another award of fees and costs post-hearing, although this is a point at which respondent's objections to interim fee and cost awards often vanishes.

⁸⁶ In her response to the Motions *in Limine*, respondent noted that, since I gave petitioners until July 2013 to file an expert medical report from Dr. Megson's replacement (Post-Hearing Order, issued May 1, 2013, at 2), the motion was moot. Res. Response at 6 (ECF No. 258). Respondent asked me to defer making a determination about hearing testimony from the substituted expert "until after the new opinion has been filed and respondent has had an opportunity to file a response." *Id.* Petitioners agreed with respondent's request, asking for a "deferral of any outstanding issues regarding additional expert testimony to the time when such testimony is proffered." Pet. Reply at 19 (ECF No. 259).

In their post-hearing memorandum ["Pet. Post-Hearing Memo"], petitioners argued that Dr. Miller's testimony should be stricken in its entirety. Pet. Post-Hearing Memo, filed May 5, 2014, at 34 (ECF No. 297). They claimed that Dr. Miller was inconsistent in her evaluation of A.K.'s medical records; that she was neither credible nor reliable; and that her testimony was "completely without foundation." *Id.*

Petitioners offered several arguments in support of their request to have Dr. Miller's testimony stricken. First, petitioners contended that her testimony was contradictory, claiming that at times she was criticizing A.K.'s physicians for failing to note certain developmental issues and at another insisting that "there are no universal predictors of autism."⁸⁷ Pet. Post-Hearing Memo, filed May 5, 2014, at 30 (ECF No. 297).⁸⁸

They claimed that during cross examination Dr. Miller was unable "to articulate the basis for her conclusions," identify "red flags" in A.K.'s early medical records, or point to any records that supported her conclusions. *Id.* They believed that Dr. Miller misinterpreted many of A.K.'s pediatric records, *see id.*, and discounted [A.K.'s parents'] observations of their son's development. *Id.* at 31.

Finally, petitioners argued that Dr. Miller's statement that evaluating motor skills was outside her area of expertise should result in her testimony being stricken, as "[a] witness cannot be permitted to claim expertise allowing her to express opinions concerning pediatric practices and then deny her own expertise in the same area." *Id.* at 31, n.17. Petitioners did not, however, cite any legal authority for striking testimony in a bench trial.

In her Response to Petitioners' Post-Hearing Memorandum ["Res. Response"], respondent countered each basis for petitioners' motion to strike. Res. Response, filed Jun. 16, 2014, at 1-3 (ECF No. 301). Respondent described Dr. Miller as "*the most qualified expert in this case* to testify regarding the onset of [A.K.]'s autism." Res. Response at 1-2 (emphasis in original). Respondent argued that petitioners' statements in their Post-Hearing Memo were "inflammatory hyperbole" in addition to being "simply untrue." Res. Response at 2. Respondent contended that Dr. Miller's testimony had an adequate foundation, given her review of medical records and home videos, the medical literature she referenced, and "her knowledge of how autism manifests during the first two years of life." Res. Response at 2.

Respondent also offered a more nuanced and factually correct view of Dr.

⁸⁷ Petitioners wrote: "Most telling in the context of Dr. Miller's criticism of AK's contemporaneous treating physicians' failure to observe AK's developmental issues at this time, was her testimony 'that there are no universal predictors of autism.' Tr. at 870, lines 1-8; 871, lines 5-9." I note that Dr. Miller did not use precise the words appearing in quotation marks, although I agree that that was the essence of her testimony. I caution petitioners against citing phrases as direct quotations when they are not.

⁸⁸ In the next page of their Post-Hearing Memo, petitioners claim that "virtually all Dr. Miller's testimony contained blanket criticism not only of AK's pediatricians, but of virtually every other medical specialist involved in his treatment, diagnosis, and care." Pet. Post-Hearing Memo at 31 (ECF 297).

Miller's testimony, stating that "Dr. Miller was not admonishing" A.K.'s physicians for failure to recognize his autistic features, because "based on what was known about autism at the time, they would not have been expected to know what to look for." *Id.* I concur. There was never a time when Dr. Miller's tone or demeanor suggested she was being critical of or condescending to the treating doctors.

Regarding petitioners' statement that Dr. Miller limited her own expertise, respondent argued that she admitted that she was not a medical doctor, and "it was therefore entirely appropriate for her to decline to offer opinions on issues involving diagnosis and treatment of [A.K.]'s physical health." *Id.* at 2-3. In respondent's view, Dr. Miller's lack of a medical degree did not render her unqualified to identify the early symptoms of autism; "[i]ndeed, her training and experience abundantly qualify her to opine on those issues." *Id.* at 3. In response to the allegation that Dr. Miller discounted parental reports of A.K. experiencing a regression, respondent argued that the physician in whose records the notation appears was unlikely to have "fact checked" A.K.'s earlier medical records and independently verify that A.K.'s parents' account was accurate. *Id.* During her testimony, Dr. Miller explained that parental reports of a regression that are given years after the fact are difficult to rely upon. *Id.*, see also Tr. at 940. In respondent's view, although Dr. Miller's testimony was damaging to petitioners' claim, it was "well-supported and reliable." *Id.*

2. Legal Standards.

a. Authority to Exclude Unreliable Evidence.

Under the Vaccine Act, a special master must consider all relevant scientific and medical evidence contained in the record, but the record itself is established by the court. 42 U.S.C. § 300aa-13(b)(1)(c). A special master must consider "all relevant and reliable evidence, governed by principles of fundamental fairness to both parties." Vaccine Rule 8(b)(1). Special masters are required to consider the record as a whole. § 13(b)(1). Taken together, these provisions have been interpreted to grant special masters the discretionary authority to exclude unreliable evidence from the record on a motion *in limine*. *Verzyer v. Sec'y, HHS*, No. 06-522V, 2010 WL 2507791, at *20-22 (Fed. Cl. Spec. Mstr. June 15, 2010), *aff'd*, 98 Fed. Cl. 214, 222 (2011)

A special master may, in her discretion, exclude evidence, but there is no statutory requirement that she do so in any particular instance. *Id.* at *19-20. Exclusion of evidence in vaccine cases is an "exceptional remedy," proper only where the opinion of the proffered expert is "completely unreliable." *Verzyer*, 2010 WL 2507791, at *21-22.

b. Determining Reliability.

Although the Federal Rules of Evidence do not apply to vaccine litigation, the factors for determining reliability of expert testimony enunciated in FRE 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) can be used as a

framework for special masters in considering the reliability of an expert's opinion. *Verzyer*, 98 Fed. Cl. at 223; see also *Cedillo*, 617 F.3d at 1339; *Terran v. Sec'y, HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). The *Daubert* factors are: (1) whether the theory has general acceptance in the scientific community; (2) whether the theory has been subjected to peer review and publication; (3) whether it can and has been tested; and (4) whether the known potential rate of error is acceptable. *Daubert*, 509 U.S. at 593-94.

A *Daubert* analysis is appropriate in any case involving "scientific, technical, or other specialized knowledge." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). The Supreme Court has cautioned fact-finders that "conclusions and methodology are not entirely distinct from one another...A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

A special master is not required to consider the *Daubert* factors when determining the reliability of expert testimony in vaccine cases (*Garcia v. Sec'y, HHS*, No. 05-720V, 2010 WL 2507793 (Fed. Cl. Spec. Mstr. May 19, 2010), at *8), but doing so may be useful when assessing "general medical issues" (*Terran*, 195 F.3d at 1316). Rarely, special masters have found an expert sufficiently unqualified and unreliable so as to warrant exclusion on respondent's motion. See *Verzyer*, 2010 WL 2507791. In *Verzyer*, the court excluded testimony from an expert who "openly flaunt[ed] that he does not follow accepted medical science," did not show any of the *Daubert* indicia of reliability, and lacked clinical experience treating patients with the same condition as the petitioner. *Verzyer*, 2010 WL 2507791, at *3, *22-23. The testimony of a second expert was also excluded; her credentials as a doctor of osteopathy and previous board-certification as a doctor of emergency medicine did not render her qualified to testify as to neurological diagnoses, and her ideas had not been subject to critical analysis by others in the field or in peer-reviewed medical journals. *Id.* at *25. The court stated that the testimony of these experts was "manifestly...unhelpful" and "thoroughly worthless," respectively, due to a lack of relevance to the resolution of the issues presented in the case. *Id.* at *25-26.

In addition to the *Daubert* factors, the court may consider an expert's qualifications to testify on particular subjects when weighing expert testimony. *Bast v. Sec'y, HHS*, No. 01-565V, 2012 WL 6858040, at *21 (Fed. Cl. Spec. Mstr. Dec. 20, 2012) (a special master may consider "any specialized knowledge, experience, training, or education of the witness that would inform the offered opinion"). When making determinations about an expert's credibility, special masters consider whether the expert's qualifications bear on the specific substantive area about which the expert is testifying.

c. Vaccine Act Practice: Evaluation and Exclusion.

Special masters routinely undertake a careful consideration of an expert's experience in a particular area. For instance, in *Pafford*, the court questioned an

expert's qualification because he lacked certification in the specialized areas about which he testified. *Pafford v. Sec'y, HHS*, 451 F.3d 1352 (Fed. Cir. 2006). Similarly, the court in *Locane* afforded greater weight to the testimony of a physician who routinely treated patients with the disease in question than it did to one who did not. *Locane v. Sec'y, HHS*, 99 Fed. Cl. 715 (2011). In *Waleryszak*, the Court of Federal Claims upheld the special master's decision to afford less weight to the testimony of a pediatrician who did not specialize in the diagnosis of neurological dysfunctions. *Waleryszak v. Sec'y, HHS*, 45 Fed. Cl. 573 (1999).

On occasion, special masters have excluded *sua sponte* the expert testimony of non-medical doctors who wished to opine on matters far removed from their areas of expertise. See, e.g., *Domeny v. Sec'y, HHS*, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. Mar. 15, 1999), *aff'd*, 232 F.3d 912 (Fed. Cir. 2000) (excluding the testimony of an expert witness with degrees in dentistry and public health who intended to opine on diagnosis and duration of petitioner's non-dental medical condition); *Ruiz v. Sec'y, HHS*, No. 02-156V, 2007 WL 5161612 (Fed. Cl. Spec. Mstr. Mar. 14, 2007) (striking the testimony of a psychologist who opined on causation after he admitted he was not trained to diagnose neurological illnesses); *Smith v. Sec'y, HHS*, No. 08-874V, 2009 WL 4020253, at *3 (Fed. Cl. Spec. Mstr. Oct. 30, 2009) (excluding the testimony of a non-medical doctor chiropractor who wished to opine on causation of fibromyalgia).

Non-medical doctors have been allowed to testify as experts in vaccine cases about issues that fall within the purview of their training and experience. See, e.g., *Snyder*, 2009 WL 332044, at *17, *19 (Dr. McCabe, a non-medical immunotoxicologist, was described as having "impeccable qualifications" in that field; similarly, Dr. MacDonald, a non-medical doctor with training in immunology who had performed extensive research on the human gastrointestinal system, was "eminently qualified to testify on diseases and immunology of the digestive system"). A proffered expert's lack of a medical degree "does not preclude his testimony as to facts commonly accepted within the scientific community to which he belongs." Pet. Post-Hearing Memorandum at 122 (citing *White v. United States*, 399 F.2d 813, 820 (8th Cir. 1968); *Harris v. Smith*, 372 F.2d 806, 813-14 (8th Cir. 1967); *Sher v. De Haven*, 91 U.S. App. D.C. 257, 199 F.2d 777, 782, cert. denied, 345 U.S. 936 (1953); *Hill v. Gonzalez*, 454 F.2d 1201, 1203 (8th Cir. 1972).

When the testimony of non-medical doctors has been excluded, it has generally been because their lack of medical degree bore some relation to their lack of experience or some other Rule 702 qualification. For example, in *Domeny*, the testimony of a dentist was excluded because he was not qualified to give an opinion about the diagnosis and duration of Guillan-Barre Syndrome. The court noted that he was not a medical doctor, and his experience in "dental behavioral science, dental public health, health education and promotion, behavioral science, humanistic psychology, psychosocial factors influencing substance abuse and oral hygiene behaviors, and the effects of marijuana smoking on cardiovascular and respiratory stress response mechanisms" was irrelevant when determining what medical condition petitioner had and for how long. *Domeny*, 1999 WL 199059, at *14. In doing so, the

court based its exclusionary authority on cases where courts “refused to let persons testify who have little experience or education in the substantive area in which they are being proffered as an expert.” *Id.* at *15 (citing *Hidden Oaks Limited v. City of Austin*, 138 F.3d 1036, 1050 (5th Cir. 1998) (upholding the trial court’s refusal to allow a witness to give expert testimony on the value of land when the witness was not a licensed appraiser or real estate broker and was unfamiliar with standard appraisal methods); *Barrett v. Atlantic Richfield Co.*, 95 F.3d 375, 382 (5th Cir. 1996) (a witness was not permitted to give expert testimony as to the scientific correlation between chemical exposure and chromosomal damage in humans due to the expert’s limited expertise and background in the subject area)). The fact that a proffered expert is not a medical doctor does not necessarily render her unqualified to opine on areas within her area of substantive expertise.

Generally, special masters consider all of the evidence and then assess its reliability in determining how much weight to afford it. *Fester v. Sec’y, HHS*, No. 10-243V, 2013 WL 5367670, at *13 n.28 (Fed. Cl. Spec. Mstr. Aug. 27, 2013). Because special masters serve as both fact-finders and judicial officers, and because they have developed an expertise that lay jurors have not, they do not need the same procedural protection that excluding testimony at the outset provides. *Garcia*, 2010 WL 2507793, at *8. When making entitlement decisions, a special master must first assess the reliability of each expert’s theory against the facts of the case and the backdrop of accepted medicine, and then comparatively weigh the competing theories for persuasiveness. *Id.*

The concept of reliability is interwoven with the causation standard in Vaccine Act cases, which requires petitioners to demonstrate a “legally *probable*” medical explanation (*Knudsen*, 35 F.3d 548-49), a “*logical* sequence of cause and effect showing that the vaccination was the reason for the injury” (*Althen v. Sec’y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)), and “onset of symptoms during a timeframe for which, given the medical understanding of the disorder’s aetiology, it is *medically acceptable* to infer causation-in-fact.” (*de Bazan*, 539 F.3d 1352. See also *Althen*, 418 F.3d at 1278. In cases under the Vaccine Act, the court is not required to conduct a threshold inquiry into reliability separate from the examination of causation in the absence of a timely motion by a party. *Garcia*, 2010 WL 2507793, at *11. In addition, if a party does not make a timely motion to exclude evidence based on a lack of reliability, their objection is waived. *Id.*

3. Applying Legal Standards to Dr. Miller’s Testimony.

Doctor Miller was eminently qualified to opine on the symptoms of ASD; how they manifest; how ASD is diagnosed; and how medical records, parental histories, diagnostic testing, and video evidence all contribute to an ASD diagnosis. She not only diagnoses ASD herself, she teaches others how to perform such diagnoses. Res. Ex. PP at 1-3; Tr. at 847-48. Psychologists, psychiatrists, developmental pediatricians, and pediatric neurologists all perform such diagnoses. See, e.g. *King*, 2010 WL 892296, at *79 (noting that “autism is considered a neurologic and a psychiatric disorder” and that

“psychologists are also often specialists who diagnose autism.”); see also *Synder*, 2009 WL 332044, at *32 (noting that “[a]ll of the disorders falling within the autism spectrum are defined by a collection of symptoms or behaviors. With the exception of Rett’s disorder, all ASDs are diagnosed by comparing behavioral symptoms exhibited by a child against an established set of broad diagnostic criteria. The diagnosis is made by direct observation, videos of the child, and from parental reports, as there is no biochemical test for ASD.”); *Dwyer*, 2010 WL 892250, *33 n.136; Tr. at 857-58 (Dr. Miller testifying about her extensive history of diagnosing patients with ASD).

Doctor Miller performs her duties at one of the premier pediatric medical facilities in the United States, the Children's Hospital of Philadelphia, in the Center for Autism Research. Tr. 847. Moreover, her opinions on onset, symptoms, and diagnosis were buttressed by those of another well-qualified witness, Bruce Cohen, M.D. Res. Ex. SS at 6, 8; Tr. 1383-87, 1148-49. She has more publications on the topic of ASD than any of petitioners’ own experts. Compare Res. Ex. PP. at 4-8 (Dr. Miller), with Pet. Ex. 62 at 4-8 (Dr. Shafir), Tr. 238 (Dr. Kendall).

In addition to her exemplary qualifications to offer opinions, she was a superb expert witness, in spite (or perhaps because) of her lack of courtroom experience. In nearly 10 years as a special master (and seven more as a criminal court trial judge), I have heard testimony from well more than 200 experts, and I would rank Dr. Miller in the top 5% of those I have heard. She was well-versed in the medical records in this case; she explained her opinions clearly and cogently, without standing on a soapbox or displaying the unfortunate tendency to be loyal to the party paying her at the expense of candor; and, even when the cross-examination bordered on being argumentative and hostile, she maintained her composure.

Qualifications aside, there are a myriad of other reasons to deny petitioners’ motion to strike her testimony. First and foremost, her testimony has already been heard. Petitioners first moved to exclude it in their post-hearing brief. Had they truly thought she lacked the qualifications to opine, they should have raised the issue prior to her testimony. This belated objection suggests that motion was based more on the damage she did to their case than on problems in either her qualifications or testimony. In *Garcia*, respondent first argued for the exclusion of an expert’s testimony in her post-hearing brief, after the testimony had already been heard. The special master concluded that respondent had waived her objection to the admission of the testimony. *Garcia*, 2010 WL 2507793, at *1. Although I elect to address the merits of the motion, I concur with the special master’s ruling in *Garcia* that such motions post-hearing are untimely.

Any deficiencies in the reliability of Dr. Miller’s testimony are more appropriately addressed in the assignment of weight to her testimony rather than its wholesale exclusion. Further, even if exclusion were proper from a procedural perspective, petitioners’ objections to the “inconsistencies” in Dr. Miller’s methodology and “lack of foundation” for her conclusions are not a basis for exclusion. Unlike the expert in *Veryzer*, Dr. Miller’s views do not contradict accepted science; indeed, they were well

supported by medical journals and other experts. I add that I heard her testimony, the cross-examination questions, and Dr. Miller's answers, and any "inconsistencies" and "lack of foundation" exist only in the perceptions of petitioners and their counsel.

I stress that although I have considered all of petitioners' objections to Dr. Miller's testimony, I have not only found that they are without merit, in many regards they are gross misrepresentations. For example, in their response to respondent's post-hearing brief, petitioners argued that Dr. Miller had criticized Dr. Rapin for not following "appropriate medical protocol" in arriving at her diagnosis. ECF No. 302 at 7. Petitioners' counsel engaged cross-examined Dr. Miller on this point, during which Dr. Miller was quite clear in stating that petitioners' counsel was incorrect in summarizing Dr. Miller's testimony as being critical of Dr. Rapin for using insufficient diagnostic criteria in A.K.'s case. Tr. 983-84. Rather, Dr. Miller testified that Dr. Rapin likely relied at least in part on parental reports, and that it is not standard medical practice to fact-check parental reports. Tr. 984-85. Petitioners characterize this as "ironic," because Dr. Miller's own diagnostic tools rely on parental reports (ECF No. 302 at 8), but there was nothing ironic in Dr. Miller's testimony. She simply offered what should be an uncontroversial observation – that parental reports can provide important information, but that not all parental reports are equally reliable. In that regard, Dr. Miller explained that parental reports can be assessed for their reliability by "drilling down" with follow up questions that call for concrete examples and by matching up parental claims to what is observed clinically. Tr. 948-50. Contrary to petitioners' argument, Dr. Miller did not testify that this was not done in A.K.'s case, only that it cannot be confirmed and therefore the reliability of those reports is an open question. I note that, given the descriptions in school and treatment records, by four years of age, A.K.'s presentation was so clearly that of a child with ASD that it was unnecessary for Dr. Rapin to question the history provided.

In another example of overreaching, petitioners argued that Dr. Miller should be discredited on the basis that she indicated that A.K.'s influenza vaccinations were not recorded in his "official" immunization record. Petitioners claim that this statement demonstrated Dr. Miller's lack of familiarity with pediatric practice. ECF No. 297 at 27-28. The point that Dr. Miller made in her report is quite clear: she wrote that she could find no notation of A.K.'s first influenza vaccination in either his "official" vaccine record, referring to the page of A.K.'s medical records constituting his "vaccine administration record" (Res. Ex. OO at 2 (citing Pet. Ex. 2, p. 2.), nor in the progress note for the visits surrounding the date at which he received the vaccine (Res. Ex. OO at 2 (citing Pet. Ex. 2, p. 21).⁸⁹ Instead, she pointed out, the influenza vaccine is only noted in a summary of vaccinations. Res. Ex. OO at 2 (citing Pet. Ex. 2, p. 1. and Pet. Ex. 61, p. 4). Unlike the administration record, the vaccine summary lacks parental signatures or an administrator signature and/or initials. Compare Pet. Ex. 2, p. 1 and p. 2. Particularly in light of Dr. Miller's clear citation to the precise record she was characterizing as

⁸⁹ Pet. Ex. 2, p. 21 contains what appear to be telephone calls on October 23, 2001 and November 16, 2001. There are no records documenting an office visit to receive a vaccination on November 2, 2001. The only other November 2001 visit was the well-child visit on November 21, 2001, and there is no mention that an influenza vaccination was ordered in that record. *Id.*, p. 20.

“official,” petitioners’ belaboring of Dr. Miller’s word choice is not a persuasive argument regarding Dr. Miller’s fitness as an expert witness.

The extent of the testimonial evidence that no vaccine record can be considered “official” was Dr. Shafir’s general umbrage at the idea that any “official” immunization record could even be thought to exist. Doctor Shafir was obviously disdainful of Dr. Miller as a non-pediatrician or even a physician, and it was this attitude, rather than any actual misunderstanding of Dr. Miller’s reference to the records, that shaped his testimony. Tr. 506-510.

Furthermore, Dr. Miller was not wrong in contending that there is an “official” vaccination record. See § 300aa-25 (requiring that each health care provider who administers a vaccination shall record in a permanent medical record or office log the date of administration, the manufacturer and lot number, the name and address of the health care provider, and other information required by regulation). The only record that meets this definition in A.K.’s case is the vaccine administration record. Even if I thought that Dr. Miller’s word choice was a poor one, there is no question as to what her underlying point was and no evidence to suggest that Dr. Miller was confused regarding the nature of the records she reviewed.⁹⁰

4. Denying Motion to Strike.

Although a special master is permitted to exclude unreliable evidence in vaccine injury cases, expert testimony is rarely excluded in its entirety unless it is completely unreliable. The special master is not required to undertake a threshold inquiry into the reliability of expert testimony, and if no timely motion is made, the parties waive any objection to inclusion of expert testimony in the record. Instead, in most cases the special master will take into account the reliability of an expert when assigning her testimony weight. In assessing the reliability of evidence already admitted, the special master may apply the principles of the Federal Rules of Evidence and *Daubert*, all of which, in this case, favor the admission of Dr. Miller’s testimony in its entirety.

Petitioners’ Motion to Strike is **DENIED**.

G. Prepayment or Preapproval of Fees.

Petitioners requested clarification and reassurances from me that they would be reimbursed for the fees and costs of their expert witness, Dr. Deth, as “they were not in a position to jeopardize their financial status by advancing large sums of money for

⁹⁰ I add that, had respondent not conceded that A.K. received the two influenza immunizations as alleged, this might have been a far different and far simpler case. As reflected in the summary of A.K.’s medical records as set forth in the entitlement decision in this case, the only record in which the initial influenza vaccination appears is the summary sheet, in spite of [A.K.’s mother’s] testimony that it was received at A.K.’s pediatrician’s office. And, there remain unanswered questions surrounding the administration of the second vaccination, but I accept respondent’s concession that it was administered as reflected in [A.K.’s mother’s] medical record.

witnesses that the Court would subsequently deny.” Motions *in Limine* at 29 (ECF No. 227).

Doctor Deth had testified on behalf of petitioners in the Theory 2 OAP test cases in support of the position that thimerosal exposure could cause autism. The special masters’ decisions in the Theory 2 test cases concluded that there was no reliable evidence to support petitioners’ theory. *Dwyer*, 2010 WL 892250; *King*, 2010 WL 892296; *Mead*, 2010 WL 892248. This included Dr. Deth’s theories about mercury causing oxidative stress which impacted on the transsulfuration cycle. The special masters were quite critical of the testimony and opinions of Dr. Deth in their decisions.

In their motion regarding payment of Dr. Deth’s expert fees and costs, petitioners explained that they were not using the same theory in their case, and moreover, that they withdrew from the OAP before the entitlement hearings in the Theory 2 test cases were conducted. Motions *in Limine* at 31 (ECF No. 227). They questioned whether I had prejudged his testimony and sought reassurance that they would be reimbursed for his appearance, as I had previously cautioned them that I did not intend to allow them to relitigate the Theory 2 cases without additional evidence. Given that, in withdrawing from the OAP and as a Theory 2 test case, petitioners had reserved the right to rely on the theories advanced in the OAP, this caution was particularly applicable to their presentations at any subsequent entitlement hearing.

Respondent noted that petitioners had not demonstrated that the amounts they requested—or even presenting Dr. Deth’s testimony at all—were reasonable. Res. Response at 5 (ECF No. 258). Respondent contended that a determination about the reasonableness of Dr. Deth’s fees could only be made once the case is concluded and “after a proper and timely costs application is filed.” *Id.* at 6.

In their Reply, petitioners acknowledged that their motion was moot, “as the funds are already expended or committed.” Pet. Reply at 18 (ECF No. 259). They noted their intent to file for interim fees and costs.

Petitioners have received two interim awards of fees and costs. See ECF Nos. 215 and 312. The total award to date is nearly \$460,000.00 dollars. This total does not include my \$5,000.00 award for advance payment of interim costs for Dr. Frye, a decision which was withdrawn when petitioners’ expert was unable to opine due to changed circumstances. See ECF Nos. 121 (decision awarding advance interim costs); 123 (respondent’s motion for reconsideration); 124 (denial of motion to reconsider); 128 (order withdrawing fees decision, based on petitioners’ report that the expert could no longer opine). None of the fees and costs awarded in these decisions was specific to Dr. Deth.

Whether Dr. Deth’s fees and costs will ultimately be paid remains an open question—one that cannot be answered until an application, supported by invoices, is made. Given the significant duplication of his OAP testimony at the hearing in this case, questions about the reasonableness of his presentation (and the hours to be paid, if at

all), are almost certain to be raised.

III. Conclusion.

The record in this case is now settled. In summary, petitioners' **motion to subpoena Dr. Zimmerman is DENIED**. Petitioners' **motion to invoke estoppel against respondent on the basis of the *Poling* Rule 4(c) report or other evidence is DENIED**. Petitioners' **motion to exclude evidence from the OAP is DENIED**. Petitioners' motion to substitute a child development expert is **MOOT**. Petitioners' motion for prepayment of fees is **MOOT**. Petitioners' **motion for leave to file additional exhibits is GRANTED IN PART AND DENIED IN PART**. Petitioners' **motion to strike the testimony of Dr. Miller is DENIED**.

IT IS SO ORDERED.

s/Denise K. Vowell

Denise K. Vowell
Special Master