

In the United States Court of Federal Claims

No. 03-0632V

Filed: February 12, 2016¹

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

Petitioners,

v.

SECRETARY OF THE DEPARTMENT
OF HEALTH AND HUMAN SERVICES,

Defendant.

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National Vaccine Injury Compensation
Program, 42 U.S.C. §§ 300aa-10 -300aa-
34;
Omnibus Autism Proceeding;
Review of Decisions by Special Masters, 42
U.S.C. § 300aa-12(e).

John F. McHugh, New York, New York, Counsel for Petitioners.

Heather L. Pearlman, United States Department of Justice, Washington, D.C., Counsel for
Respondent.

MEMORANDUM OPINION AND FINAL ORDER REGARDING PETITIONERS' MOTION FOR REVIEW

BRADEN, *Judge*.

¹ This Memorandum Opinion And Final Order was issued on December 18, 2015. The parties were given until January 4, 2016 to file proposed redactions. The parties were required to submit proposed redactions on January 4, 2016. On December 31, 2015, Petitioners filed a: Motion To Stay Publication Of Decision; a Notice Of Filing Redactions; and a Motion For Review Of The Special Master's December 1, 2015 Ruling On Redaction Request And Change Of Case Caption. On January 19, 2016, the court granted Petitioners' Motion To Stay Publication, pending its resolution of Petitioners' Motion For Review. On February 12, 2016, the court issued a Memorandum Opinion And Final Order on Petitioners' December 31, 2015 Motion For Review. Based on that Opinion, the court has replaced Petitioners' actual names with initials in this Memorandum Opinion And Final Order.

I. RELEVANT FACTUAL BACKGROUND.²

A.K. was born on November 9, 1999 to R.K. and L.K. (collectively, the “Petitioners”). Pet. Ex. 61 at 2. When A.K. was about 18 months of age, Petitioners became concerned that A.K.’s speech was delayed. Dec. at 88. On November 2, 2001 and December 3, 2001, A.K. received influenza vaccinations around his second birthday. *Id.* at 11. On November 21, 2001, A.K.’s medical records explicitly noted speech delay during his two year visit. *Id.* at 89.

On September 22, 2002, Dr. Marvin Boris, A.K.’s primary pediatrician, indicated that A.K. might have Autism Spectrum Disorder (“ASD”). *Id.* at 13. From 2002 to 2003, A.K. was treated for various gastrointestinal problems. *Id.* at 14. On April 22, 2004, A.K. was formally diagnosed with ASD. *Id.*

On November 20, 2008, A.K. was diagnosed with “probabl[e] mitochondrial encephalomyopathy[.]” Pet. Ex. 32 at 3.

II. PROCEDURAL HISTORY.

A. As Part Of The Omnibus Autism Proceedings.

On March 24, 2003, Petitioners filed a Short-Form Petition for Vaccine Compensation under the National Childhood Vaccine Injury Act, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa–10 *et seq.* (the “Vaccine Act”). By filing a Short-Form Petition, Petitioners opted into the Omnibus Autism Proceeding. Ruling at 2.

On April 9, 2003, the Special Master issued a Notice Regarding ‘Omnibus Autism Proceedings’ to stay this case while discovery in the Omnibus Autism Proceeding was conducted.

On June 23, 2003, the Secretary of Health and Human Services (“the Government”) filed a Respondent’s Report, stating that the Short-Form Petition “failed to state with particularity the circumstances surrounding the claim and was not accompanied by materials required[.]” Dkt. No. 4.

On December 17, 2003, the Special Master issued an Order suspending proceedings for no longer than 180 days.

On May 21, 2004, the Special Master issued another Order, stating that “[P]etitioner may submit a notice in writing choosing to continue or to withdraw the petition . . . and such notice shall be filed within 30 days[.]” Dkt. No. 8 (internal quotations omitted).

On June 10, 2004, Petitioners filed a Notice Of Intent To Continue The Petition In Autism Case. Nothing transpired for almost three years.

² The relevant facts herein were derived from: the Special Master’s September 28, 2015 Decision (“Dec.”), Dkt. No. 320; the September 28, 2015 Ruling On Motions (“Ruling”), Dkt. No. 319; the Petitioners’ Exhibits (“Pet. Exs. 1–240”); and the Government’s Exhibits (“Gov’t Exs. A–LLL”).

On March 22, 2007, the case was reassigned to another Special Master.

On December 18, 2007, the case was reassigned to yet another Special Master.

On January 8, 2008, Petitioners filed a Consented Motion To Substitute Attorney Thomas B. Powers In Place Of Steven B. Tannenbaum. On January 22, 2008, Petitioners filed the Expert Report of Dr. Elizabeth A. Mumper, M.D., as Pet. Ex. 1. On January 31, 2008, Petitioners filed a Notice Of Filing Compact Disc. The disc contained the medical records of A.K. and were filed as Pet. Exs. 2–12.

On February 5, 2008, the Government filed a First Motion To Produce Videotapes. Specifically, the Government requested “all videotapes of [A.K.] from birth to age four years.” Dkt. No. 19. On February 8, 2008, the Special Master issued an Order, requiring Petitioners to “make any videotapes containing footage of [A.K.] from birth to age four available” to the Government. Dkt. No. 22. The Special Master, however, required the Government to “redact the copied videos to frames containing [A.K.] and any individuals interacting with [A.K.]” before filing the videotapes with the court. Dkt. No. 22. On February 8, 2008, the Government filed relevant medical literature as Gov’t Exs. A–F. On February 14, 2008, Petitioners filed a Notice Of Filing Compact Disc. The disc contained more of A.K.’s medical records and were filed as Pet. Exs. 3 Supp., 13–21.

On February 25, 2008, the Government filed a Notice Of Filing Exhibits On Compact Disc. The disc contained the expert reports and *curricula vitae* of: Dr. Jeffrey Brent, M.D., Ph.D.; Dr. Manuel F. Casanova, M.D.; Dr. Thomas W. Clarkson, Ph.D., M.D.; Dr. Eric Fombonne, M.D., F.R.C.Psych.; Dr. Steven N. Goodman, M.D., M.H.S., Ph.D.; Dr. Jeffrey A. Johnson, Ph.D.; Dr. Dean P. Jones, Ph.D.; Dr. Thomas L. Kemper, M.D.; Dr. Catherine Lord, Ph.D.; Dr. László Magos, M.D., D.C.P., F.R.C.Path.; Dr. Richard B. Mailman, Ph.D.; Dr. L. Jackson Roberts, II, M.D.; Dr. Patricia M. Rodier, Ph.D.; and Dr. and Professor Sir Michael Rutter, M.D., F.R.C.Psych. These expert reports and *curricula vitae* were filed as Gov’t Exs. G–HH.

On March 14, 2008, the Government submitted the expert report and *curriculum vitae* of Dr. Robert Rust, Jr., M.D., M.A., as Gov’t Exs. II–JJ. On March 19, 2008, the Government filed another expert report from Dr. Robert Rust, Jr., M.D., M.A., as Gov’t Ex. KK. On March 20, 2008, Petitioners filed the expert reports of: Dr. Richard C. Deth, Ph.D.; Dr. Sander Greenland, M.A., M.S., Dr.P.H.; and Dr. H. Vasken Aposhian, Ph.D. These expert reports were filed as Pet. Exs. 22–24. On March 25, 2008, Petitioners filed a Notice Of Filing Supplemental Medical Records On Compact Disc. The disc supplemented Pet. Exs. 4 and 10, and provided Pet. Exs. 25–30.

B. As An Individual Test Case.

On April 10, 2008, Petitioners filed a Motion, requesting that Petitioners’ claim be withdrawn from the Omnibus Autism Proceeding “in order to proceed to an individual hearing on compensation.” Dkt. No. 40. On April 18, 2008, the Special Master granted the April 10, 2008 Motion to allow the case to proceed as an individual case.

On May 22, 2008, Petitioners filed a Consented Motion To Substitute Attorney R.K. In Place Of Tom Powers, which the Special Master granted on May 23, 2008.

On July 8, 2008, the Government filed a Motion To Withdraw Expert Reports Exhibit K (Dr. Thomas Clarkson's Expert Report), Exhibit L (Dr. Clarkson's *curriculum vitae*), Exhibit Y (Dr. László Magos's Expert Report), and Exhibit Z (Dr. Magos's *curriculum vitae*). On July 29, 2008, the Special Master granted the Government's Motion To Withdraw Expert Reports.

On January 15, 2009, Petitioners filed A.K.'s medical record as Pet. Ex. 31. On January 16, 2009, Petitioners filed A.K.'s medical records produced by Dr. John Shoffner, as Pet. Ex. 32.

On March 3, 2009, June 22, 2009, and August 4, 2009, Petitioners filed Motions For Extension Of Time To Produce Additional Records And Report On Status Of Retaining Counsel. The Special Master granted these Motions on March 12, 2009, July 6, 2009, and August 4, 2009.

On August 14, 2009, Petitioners filed additional medical records as Pet. Ex. 33.

On October 16, 2009, Petitioners filed another Motion For Extension Of Time, which the Special Master granted on October 19, 2009.

On December 2, 2009, Petitioners filed a Consented Motion To Substitute John F. McHugh In Place Of R.K. The Special Master granted the Consented Motion on January 7, 2010.

On June 8, 2010, the Special Master issued a Scheduling Order, requiring Petitioners to file: medical records by June 18, 2010; an interim fees application by July 23, 2010; and a Status Report by August 9, 2010. Dkt. No. 79. On June 14, 2010, Petitioners refiled Exhibits 27–33 and filed A.K.'s medical records as Pet. Exs. 34–35. On June 16, 2010, Petitioners filed additional medical records as Pet. Ex. 36.

On August 18, 2010, the Special Master issued an Order, requiring Petitioners to identify their “potential expert by August 27, 2010 and outline the steps taken to contact the expert to date.” Dkt. No. 97.

On September 3, 2010, the Special Master issued an Order To Show Cause, because “Petitioners failed to respond to [the August 18, 2010 Order]. . . . [P]etitioners have been granted several opportunities to identify experts and submit their reports. . . . Petitioners cannot prevail in this causation in fact case without the opinion of a qualified expert causally linking [A.K.'s] diagnosis to his vaccinations.” Dkt. No. 98. The Order required Petitioners to “comply with [the] August 18, 2010 [O]rder . . . or otherwise show cause by Monday, October 4, 2010, why this case should not be dismissed for failure to prosecute.” Dkt. No. 98.

On October 13, 2010, the Special Master issued a Decision, dismissing the case for the Petitioners' failure to respond. On October 26, 2010, Petitioners filed a Motion For Relief and Reconsideration Of Decision Dated October 13, 2010. Petitioners attached Pet. Exs. 37–56 to their Motion. On October 29, 2010, Petitioners filed a Motion To Redact The October 13, 2010 Decision.

On November 3, 2010, the Government filed a Response To Petitioners' October 26, 2010 Motion For Reconsideration. On November 5, 2010, the Government filed a Response to Petitioners' October 29, 2010 Motion To Redact. On November 6, 2010, Petitioners filed a Reply To the Government's November 3, 2010 Response. The Petitioners attached Pet. Exs. 57–58 to their Reply. On November 12, 2010, the Special Master issued an Order, granting Petitioners' Motion For Reconsideration and denying as moot Petitioners' Motion To Redact. On November 24, 2010, Petitioners filed a Motion To Redact The November 12, 2010 Order and attached Pet. Ex. 59 to this Motion. On November 30, 2010, Petitioners filed a Motion To Amend Schedule And Award Interim Cost Of Expert Witnesses.

On December 10, 2010, the Government filed a Response To Petitioners' November 24, 2010 Motion To Redact. On December 13, 2010, the Special Master issued an Order, requiring the parties to brief “how the E-Government Act of 2002 § 205, 44 U.S.C. § 3501 (2006) impacts whether the [November 12, 2010] order should be disclosed, and if so, whether [P]etitioners' requested redactions should be granted.” Dkt. No. 112. On December 14, 2010, the Government filed a Response to Petitioners' November 30, 2010 Motion To Amend Schedule And Award Interim Cost Of Expert Witnesses. On December 23, 2010, Petitioners filed two Motions To Amend Schedule that the Special Master granted that same day. The Government also filed a Response To The Special Master's December 13, 2010 Order. On December 30, 2010, Petitioners filed a Response To The Special Master's December 13, 2010 Order.

On January 10, 2011, the Special Master issued an Order On Motion To Redact, granting in part and denying in part Petitioners' November 24, 2010 Motion To Redact. On January 13, 2011, Petitioners filed a Reply To The Government's December 14, 2010 Response To Petitioners' Motion To Amend Schedule And Award Interim Cost Of Expert Witnesses. Petitioners also attached Pet. Ex. 60 to their Reply. On January 28, 2011, the Special Master issued a Decision Awarding Interim Costs. Specifically, the Petitioners were awarded \$5,000. Dkt. No. 121. The Decision required Petitioners to file an Amended Petition by February 29, 2011 and an expert report by March 29, 2011. Dkt. No. 121.

On February 7, 2011, the Government filed a Motion For Reconsideration Regarding The January 28, 2011 Decision Awarding Interim Costs. The Special Master denied the Motion on February 23, 2011. On February 24, 2011, Petitioners filed A.K.'s medical records as Pet. Ex. 61. On February 28, 2011, Petitioners filed an Amended Petition. The Amended Petition alleged that “two pediatric influenza vaccinations (12.5 ml dose) given to [A.K.] . . . resulted in an encephalopathy.” Dkt. No. 126. On February 28, 2011, the Special Master issued an Order that withdrew the January 28, 2011 Decision Awarding Interim Costs. The Special Master also explained, “[o]n February 28, 2011, [P]etitioners informed me . . . that Dr. Frye is not available to opine in this case[.] As my decision awarding interim costs pertained to the retention of Dr. Frye specifically, it is now moot.” Dkt. No. 128.

On July 7, 2011, Petitioners filed the Expert Report of Dr. Yuval Shafrir, M.D., as Pet. Ex. 63.

On August 4, 2011, Petitioners filed additional medical records of A.K. as Pet. Ex. 64.

On October 11, 2011, the Government filed Omnibus Autism Proceeding Evidence Concerning Autism Spectrum Disorders as Gov't Ex. LL.

On November 14, 2011, the Government filed: the Expert Report of Dr. Gerald Raymond, M.D.; various medical articles; the *curriculum vitae* of Dr. Gerald Raymond, M.D.; the Expert Report of Dr. Judith Miller, Ph.D.; the *curriculum vitae* of Dr. Judith Miller, Ph.D.; and the Expert Report of Dr. Christine McCusker, M.D. These documents were filed as Gov't Exs. MM–RR.

On December 19, 2011, Petitioners filed the Expert Report of Dr. Fran D. Kendall, M.D. and the references cited therein as Pet. Exs. 65–92.

On March 13, 2012, the Government filed the expert reports and *curricula vitae* of Dr. Bruce H. Cohen, M.D. and Dr. Kendall B. Wallace, Ph.D. as well Gov't Exs. SS–VV.

On July 31, 2012, Petitioners filed a Status Report and attached the *curricula vitae* of Dr. Richard C. Deth, Ph.D. and Dr. Mary Norfleet Megson, M.D. The *curricula vitae* were filed out of order as Pet. Exs. 95–96.

On August 2, 2012, Petitioners filed medical records as Pet. Ex. 31A and Pet. Exs. 93–94. On August 12, 2012, Petitioners filed additional medical literature as Pet. Exs. 97–106. On August 16, 2012, the Special Master issued a Pre-Hearing Order and scheduled a hearing in New York, New York on December 12–13, 2012 and an Expert Witness hearing in Washington, D.C., on April 22–30, 2013.

On September 24, 2012, Petitioners filed a Motion To Amend Schedule And Notice Of Intent To File On Compact Disc with the expert reports of Dr. Megson and Dr. Zirin as Pet. Exs. 107–08. On September 26, 2012, the Special Master granted the Motion To Amend.

On October 1, 2012, Petitioners filed a Notice Of Filing Of DVDs as Pet. Exs. 106–116. On October 29, 2012, Petitioners filed the Expert Report of Dr. Deth as Pet. Ex. 117.

On December 12, 2012, the Special Master held a hearing in New York, New York (“12/12/2012 TR 1–135”). That same day, Petitioners filed additional medical records of A.K. as Pet. Ex. 118.

On January 10, 2013, Petitioners filed a Motion For Interim Payment Of Anticipated Costs Of Experts And Related Expenses Necessary For The Hearing Scheduled For April 22, 2013 Through April 30, 2013. On January 28, 2013, the Government filed a Response. On February 8, 2013, Petitioners filed a Reply and attached Pet. Exs. 119–121. On January 31, 2013, the Government filed the *curricula vitae* and expert reports of Dr. Jeffrey A. Johnson, Ph.D., and Dr. Dean P. Jones, Ph.D., as well as medical literature as Gov't Exs. WW–ZZ.

On March 7, 2013, Petitioners filed invoices as Pet. Exs. 122–23. On March 22, 2013, the Government filed supplements to Gov't Exs. MM, OO, SS, UU, and VV. On March 24, 2013, Petitioners filed a Notice Of Intent To File On Compact Disc. The disc contained medical literature and was filed as Pet. Exs. 124–232.

On March 27, 2013, the Special Master issued a Decision Awarding \$24,108.12 Interim Costs. Dkt. No. 215. On March 31, 2013, Petitioners filed a Motion For Leave To Serve Deposition Subpoena. That same day, Petitioners also filed medical literature as Pet. Ex. 233.

On April 4, 2013, Petitioners filed medical literature as Pet. Ex. 234. On April 8, 2013, the Government filed a Response To Petitioners' March 31, 2013 Motion For Leave. That same day, Petitioners filed a Motion In Limine; a Motion For Judicial Estoppel; a Motion To Preclude Admission of Omnibus Autism Proceeding Evidence; a Motion For Clarification; and a Motion To Allow Petitioners To File An Expert Report And Testimony. On April 9, 2013, Petitioners filed medical literature as Pet. Ex. 235. On April 10, 2013, the Government filed an updated *curriculum vitae* of Dr. Gerald V. Raymond, M.D. as Gov't Ex. NN, Tab 1. On April 12, 2013, Petitioners filed a Notice Of Intent To File On Hard Disk Drive as Pet. Ex. 236 and Pet. Ex. 236A.

On April 17, 2013, Petitioners filed a Second Amended Petition, alleging that the two influenza vaccinations "either resulted in an encephalopathy or significantly aggravated an existing condition." Dkt. No. 237. That same day, the Government filed Gov't Ex. AAA. On April 18, 2013, Petitioners filed Pet. Ex. 237. On April 19, 2013, the Government filed Gov't Ex. BBB. On April 22–26, and April 29, 2013, the Special Master convened a hearing in Washington, D.C. ("4/22/2013 TR 136–337; 4/23/2013 TR 338–591; 4/24/2013 TR 592–841; 4/25/2013 TR 842–1232/1299; 4/26/2013 TR 1300–1520/1599; 4/29/2013 TR 1600–1783"). On April 24, 2013, Petitioners filed an additional document as Pet. Ex. 239 and Pet. Ex. 240. On April 26, 2013, the Government filed Gov't Exs. CCC–FFF. On April 29, 2013, the Government filed Gov't Ex. TT, Tab 1 and Gov't Exs. GGG–III.

On May 1 and 31, 2013, Petitioners filed supplemental slides as Pet. Ex. 239 Supp.

On August 28, 2013, the Government filed Gov't Ex. JJJ.

On September 9, 2013, the Special Master issued a Post-Hearing Order, requiring Petitioners to file any additional evidentiary filings by October 9, 2013 and the Government to file any additional evidentiary filings by November 8, 2013. On September 30, 2013, the Government filed a Supplemental Expert Report of Dr. Bruce Cohen and Dr. Kendall Wallace. These reports were filed as Gov. Exs. KKK–LLL.

On October 3, 2013, Petitioners filed a Supplemental Report by Dr. Fran Kendall as Pet. Ex. 238.

On November 15, 2013, the Special Master issued another Post-Hearing Order, requiring the parties to file post-hearing briefs by January 14, 2014.

On January 27, 2014, March 4, 2014, March 28, 2014, and April 7, 2014, Petitioners filed Motions To Amend Schedule, requesting that the Special Master extend the due date for post-hearing briefs. On January 27, 2014, March 4, 2014, March 28, 2014, and April 8, 2014, the Special Master granted these Motions.

On May 5, 2014, the Government filed a Post-Hearing Brief ("Gov't PH."). That same day, Petitioners filed a Post-Hearing Brief ("Pet. PH."). In Petitioners' Post-Hearing Brief, they

requested that Dr. Miller’s testimony “be excluded as evidence[.]” Pet. PH at 34. The Special Master interpreted Petitioners’ request as a Motion To Strike. Ruling at 48–49. On May 15, 2014, the Special Master also issued an Order, requiring that the parties file Responses to the opposing party’s brief by June 16, 2014. On June 16, 2014, the Government and Petitioners filed Responses.

On September 28, 2015, the Special Master issued a Ruling on Motions and a Decision. That same day, the case was reassigned to another Special Master.

On October 13, 2015, Petitioners filed a Motion To Redact The September 28, 2015 Decision. On October 28, 2015, Petitioners filed a Motion For Review and Memorandum In Support Of The Motion For Review (“Pet. Mem.”). That same day, the case was assigned to Judge Marian Blank Horn. On October 30, 2015, the Government filed a Response To Petitioners’ October 13, 2015 Motion To Redact. On November 6, 2015, Petitioners filed a Reply To the Government’s October 30, 2015 Response. That same day, the case was transferred to the undersigned judge.

On December 1, 2015, the Special Master issued an Order granting in part and denying in part Petitioners’ October 13, 2015 Motion To Redact. On December 2, 2015, the Special Master issued an Order Regarding Redaction Of Material Improperly Filed By Petitioners. On December 3, 2015, the Special Master issued an Order, requiring Petitioners to file copies of documents “with circles or highlighting the names of the Petitioners, whenever such names are mentioned” within 30 days. Dkt. No. 340.

III. DISCUSSION.

A. Jurisdiction.

The United States Court of Federal Claims has jurisdiction to review the decision of a Special Master in a vaccine-related injury case, pursuant to 42 U.S.C. § 300aa–12(e)(2)³ and Vaccine Rule 23(a).⁴ After reviewing the Special Master’s decision, the court may:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,
- (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law,
- or

³ Section 300aa-12(e)(2) of the Vaccine Act provides: “[W]ith respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings[.]” 42 U.S.C. § 300aa–12(e)(2).

⁴ Vaccine Rule 23(a) provides: “To obtain review of the [S]pecial [M]aster’s decision, a party must file a motion for review with the clerk within 30 days after the date the decision is filed.” Vaccine Rule 23(a).

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); *see also* Vaccine Rule 27 (same).

B. Standard Of Review.

The United States Court of Federal Claims may set aside the decision of a Special Master if findings of fact or conclusions of law are found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 42 U.S.C. § 300aa-12(e)(2)(B). “Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the ‘not in accordance with law’ standard; and discretionary rulings under the abuse of discretion standard. The latter will rarely come into play except where the special master excludes evidence.” *Munn v. Sec’y of Dep’t. of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

C. The Elements And Burden Of Proof In Vaccine Act Cases.

The Vaccine Act provides that a petitioner may receive compensation and other relief under the Vaccine Injury Compensation Program (“Vaccine Program”), if injury can be established either by causation in law or causation in fact. Causation in law is established if one of the vaccines listed in the Vaccine Injury Table at 42 U.S.C. § 300aa-14(a) (“Vaccine Table”) was administered to a petitioner, and the “first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths” of specific adverse medical conditions associated with the use of each vaccine occurred within a time period specified in the Vaccine Table. *See* 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a). The Vaccine Table is to be read and interpreted by reference to “Qualifications and aids to interpretation,” that define the key terms used therein. *Id.*

Congress also afforded a petitioner the opportunity to receive relief under the Vaccine Program, even if the time period for the first symptom or manifestation of a specified injury is not listed in the Vaccine Table. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(ii), § 300aa-13. These types of injuries are known as “off-Table” vaccine injuries. Under these circumstances, a petitioner must establish causation in fact, by offering sufficient facts to establish each element of a vaccine injury claim, and meeting the burden of proof as to each element of the claim by a “preponderance of the evidence” standard. *See* 42 U.S.C. §§ 300aa-13. Accordingly, an off-Table petitioner must proffer at least some evidence as to each element of the claim and sufficient evidence to persuade the Special Master or court by a preponderance of evidence. *Id.*

In *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317 (Fed. Cir. 2006), the United States Court of Appeals for the Federal Circuit re-affirmed the three-part test established in *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (“*Althen*”), for determining causation in fact in off-Table vaccine injury cases. *Althen* requires a petitioner to:

show by preponderant evidence that the vaccination brought about [the] injury by providing:

- (1) a medical theory causally connecting the vaccination and the injury;

- (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
- (3) a showing of a proximate temporal relationship between vaccination and injury.

418 F.3d at 1278.

If a petitioner is able to establish causation in fact, then the burden of proof shifts to the Government to establish that a factor unrelated to the vaccine was the actual cause of the petitioner's injury. *See* 42 U.S.C. § 300aa-13(a)(1)(B); *see also Althen*, 418 F.3d at 1278 ("If [a petitioner] satisfies this burden, she is entitled to recover unless the [the Government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.").

D. The Special Master's September 28, 2015 Decision.

In a 161-page decision, the Special Master addressed three issues: whether the influenza vaccinations aggravated A.K.'s underlying mitochondrial disorder; whether A.K.'s ASD predated the influenza vaccinations; and whether Petitioners' theories of causation met the preponderance of the evidence standard. Dec. at 9.

First, the Special Master determined that Petitioners had not sufficiently established that A.K. had an underlying mitochondrial disorder.⁵ Dec. at 46. To reach this conclusion, the Special Master examined the expert evidence the parties provided. Both parties' experts agreed that there is much uncertainty in diagnosing mitochondrial disorders and that the field has not yet come to a consensus on a standardized criteria. Dec. at 49; *see also* 4/22/2013 TR 249–49 (direct examination of Dr. Frances Kendall, Petitioners' expert); *see also* 4/26/2013 TR 1351 (cross examination of Dr. Bruce Cohen, the Government's expert). Nevertheless, Petitioners proffered two primary pieces of evidence.

The first piece is a diagnosis from Dr. John Shoffner, who after performing a series of tests and reviewing the results, diagnosed A.K. with "probabl[e] mitochondrial encephalomyopathy."

⁵ Mitochondrial disorders occur, because

the mitochondria cannot efficiently turn sugar and oxygen into energy, so the cells do not work correctly. . . . There are many types of mitochondrial disease, and they can affect different parts of the body: the brain, kidneys, muscles, heart, eyes, ears, and others. . . . They can affect those part(s) mildly or very seriously. Not everyone with a mitochondrial disease will show symptoms. However, when discussing the group of mitochondrial diseases that tend to affect children, symptoms usually appear in the toddler and preschool years. Mitochondrial diseases and disorders are the same thing.

Mitochondrial Disease—Frequently Asked Questions, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/ncbddd/autism/mitochondrial-faq.html> (last visited Dec. 18, 2015).

Pet. Ex. 32, at 3. The second piece was an expert opinion from Dr. Frances Kendall, who supported Dr. Shoffner's diagnosis, concluding that "clinical features and laboratory data collected to date provide support for a definitive or highly probable mitochondrial disease[.]" Pet. Ex. 65 at 7. Dr. Kendall used the Bernier criteria, a diagnostic tool used to evaluate mitochondrial disease. Pet. Ex. 65 at 7; *see also* Dec. at 49. On cross examination, however, Dr. Kendall admitted that "she could not reach a definite mitochondrial disorder diagnosis by applying the Bernier criteria." Dec. at 50 (citing 4/22/2013 TR 319) ("COUNSEL: So is it still your position that the data and the clinical features support a definitive or highly probable mitochondrial disease diagnosis? DR. KENDALL: I would say probably probable . . . with the understanding it's not definitive."). Two of Petitioners' other experts discussed mitochondrial disorders, but "both indicated that they deferred to other experts on the diagnosis of mitochondrial disorder." Dec. at 49 n. 117.

The Special Master also analyzed Dr. Kendall's interpretation of the Bernier criteria⁶ together with three indicators: enzymology results, metabolic indicators, and clinical features. Dec. at 54. The Special Master found that while enzymology would support a mitochondrial disorder diagnosis, "A.K.'s results [did] not fall low enough to be considered an abnormal finding under Bernier[.]" Dec. at 54. With respect to metabolic indicators, Dr. Kendall stated that "persistent, significant elevations in lactate" indicate mitochondrial disorder. Dec. at 57 (quoting Pet. Ex. 65, at 5). Dr. Kendall, however, "acknowledged that a single instance of elevated lactic acid compared to multiple instances of normal findings would not be indicative of persistent, significant elevation." Dec. at 58 (citing 4/22/2013 TR 316). With respect to clinical features, the Special Master did "not see any indication that Dr. Kendall would diagnose a mitochondrial disorder based on clinical features alone." Dec. at 63. The Special Master also found that Petitioners' experts collectively did "not reflect any independent application of the diagnostic standards of any interpretive analysis of Dr. Shoffner's findings." Dec. at 65.

Because Petitioner's primary mitochondrial disorder expert, Dr. Kendall, changed her opinion on the probability of A.K.'s mitochondrial disorder diagnosis, the Special Master determined that Petitioners did not establish that A.K. had an underlying mitochondrial disorder.

Second, the Special Master determined that A.K.'s ASD⁷ was not temporally related to his vaccinations, because the Special Master found evidence that A.K.'s ASD symptoms predated the

⁶ The Bernier criteria is a diagnostic standard for mitochondrial disease. It is a checklist "of typical symptoms, family history, findings on exam, biochemistry, neuro-imaging and lab testing." Amy Goldstein, M.D., *Mitochondrial Diseases*, CHILD NEUROLOGY FOUNDATION, <http://www.childneurologyfoundation.org/disorders/mitochondrial-diseases/> (last visited Dec. 18, 2015).

⁷ ASD is characterized by:

Persistent deficits in social communication and social interaction across multiple contexts; Restricted, repetitive patterns of behavior, interests, or activities; Symptoms must be presented in the early developmental period (typically recognized in the first two years of life); and Symptoms cause clinically significant impairment in social, occupational, or other important areas of current functioning.

2001 influenza vaccinations. Dec. at 68. Here, the Special Master considered the testimony of Dr. Judith Miller for the Government and Dr. Yuval Shafrir for Petitioners. Dec. at 68–69.

Dr. Miller concluded that A.K. demonstrated symptoms of ASD before A.K. received the influenza vaccinations. Dec. at 77. To reach this conclusion, Dr. Miller relied primarily on analysis of home videos of A.K. rather than A.K.’s pediatricians’ clinical observations. Dec. at 71–72. This is because “at the time A.K. experienced the onset of his ASD, screening techniques for one to two year [olds] were not yet available.” Dec. at 71 (citing 4/25/2012 TR 1047–50). Dr. Miller noted that home videos as far back as January 2001 demonstrated that A.K. had ASD. Dec. at 77. Specifically, Dr. Miller testified that, in a June 2001 home video, A.K. did not demonstrate “age appropriate, purposeful play with [a] [baseball] bat.” Dec. at 77. In another video, dated August 26, 2002, A.K. failed to respond to his name several times, a “big red flag” in terms of ASD screening. Dec. at 88 (citing 4/25/2012 TR 1008 (cross examination of Dr. Miller)). In a November 9, 2001 video, A.K. displayed ASD behaviors such as a cognitive inability to recognize that a wrapped birthday present was for him and seemed more focused on the wrapping paper and his face did not register any emotional change when the new toy was revealed. Dec. at 75 (citing 4/25/2012 TR 904–07 (direct examination of Dr. Miller)).

In contrast, Petitioners’ expert, Dr. Shafrir, ended his specialized training in ASD in 2000—well before the developments in the field Dr. Miller described. 4/23/2012 TR 525 (cross examination of Dr. Shafrir). Dr. Shafrir concluded “that the videos show no signs of ASD prior to November 10, 2001 and that the November 10 footage shows a dramatic overnight change compared to footage recorded the day before on November 9, 2001.” Dec. at 73. Dr. Shafrir testified that the change in A.K.’s behavior between November 9 and 10, 2001 was “the most dramatic appearance of behavior change I’ve seen in my career.” 4/23/2012 TR 528. The Special Master, however, noted that “[P]etitioners’ other experts did not appear to find the same significance in the November 9 and 10 videos.” Dec. at 76. A.K.’s parents also testified that they did not think A.K.’s behavior change between November 9 and 10 was dramatic. Dec. at 95. Moreover, one of Petitioners’ own experts who submitted a report, Dr. Mary N. Megson, corroborated Dr. Miller’s conclusion and contradicted Dr. Shafrir’s. Dec. at 79. Specifically, in her report, Dr. Megson wrote, “from 16–24 months of age, [A.K.] seem[ed] to plateau in his level of alertness and processing language.” Pet. Ex. 107, at 6. Dr. Kendall, another of Petitioners’ experts, observed that “A.K. demonstrated speech delay in the videos at 18 months of age[.]” Dec. at 88.

Based on this record, the Special Master concluded that “A.K. experienced . . . a gradual manifestation of ASD which could be observed long before he was administered either of the two doses of influenza vaccine in . . . 2001.” Dec. at 94–95. In reaching this conclusion, the Special Master found that “Dr. Miller’s presentation regarding the proper screening and diagnosis for ASD is not only acceptable, it was in fact far more extensive, better supported, and far more credible than Dr. Shafrir’s testimony on the same topics.” Dec. at 70.

What Is Autism Spectrum Disorder?, NAT’L INST. MENTAL HEALTH, <http://www.nimh.nih.gov/health/topics/autism-spectrum-disorders-asd/index.shtml> (last visited Dec. 18, 2015).

Third, the Special Master addressed Petitioners' theories of causation. Petitioners argued that "A.K.[s] mitochondrial defect renders him particularly susceptible to oxidative stress, which was activated by the two doses of trivalent influenza vaccine, thereby causing his decompensation and severe developmental regression." Pet. PH at 4. To support their argument, Petitioners offered two different theories of causation.

First, Dr. Kendall testified that A.K.'s mitochondrial disorder could induce "periods of decompensation or deterioration[.]" Dec. at 97 (citing Pet. Ex. 65, at 7). The influenza vaccinations aggravated the mitochondrial disorder, resulting in developmental regression. Dec. at 97 (citing Pet. Ex. 65, at 8). The Special Master noted, however, that "[t]he evidence that mitochondrial deterioration can be linked . . . to vaccines is largely anecdotal, and the evidence that mitochondrial decompensation looks like ASD is nearly non-existent." Dec. at 97. In particular, the Special Master criticized Dr. Kendall's reliance on an article about *Poling v. Sec'y of Health & Human Servs.*, 2008 WL 1883059 (Fed. Cl. Spec. Mstr. April 10, 2008). Dec. at 101. The *Poling* case report studied "a child who regressed after receiving vaccines at 19 months of age and who was subsequently diagnosed with both ASD and a mitochondrial disorder." Dec. at 101. The Special Master surmised that "[t]he *Poling* case study is merely a single instance A single case study in isolation is not significant proof[.]" Dec. at 107. Moreover, the *Poling* petitioner's condition arose after receiving multiple vaccinations—none of which were for influenza. Dec. at 108–09. The Special Master also critiqued Dr. Kendall's reliance on a paper by Dr. Shoffner. Dec. at 110. The Shoffner paper, however, "did not find that a vaccination was temporally associated with autistic regression in the absence of fever." Dec. at 103 (citing 4/22/2013 TR 331–32). "[A]bsent an understanding of how or why fever can cause a mitochondrial deterioration, the conclusions one can draw from . . . the Shoffner article are severely limited[.]" Dec. at 104.

Second, Dr. Shafrir posited a "triple hit" hypothesis—that "A.K. had a mitochondrial disorder, a MTHFR polymorphism, and a genetically-determined abnormal immune system . . . which . . . combined with his influenza vaccination, caused an autoimmune brain injury (encephalopathy) which manifested as an autistic regression." Dec. at 111 (citing Pet. Ex. 63 at 14–18). The Special Master, however, noted that Dr. Shafrir "failed to produce any evidence that A.K. had a brain injury caused by a vaccine reaction." Dec. at 132. Moreover, Dr. Shafrir conceded that "he could not say that A.K.'s MTHFR polymorphisms caused A.K.'s autism[.]" Dec. at 120.

Third, Dr. Richard C. Deth testified in support of Dr. Kendall's and Dr. Shafrir's theories. Dr. Deth concluded that "vaccinations promote inflammation and oxidative stress[.]" Dec. at 133 (quoting 4/24/2013 TR 751). The Special Master, however, did not find Dr. Deth to be credible. Dec. at 133. This is because Dr. Deth "failed to mention that data he was presenting was potentially contradicted by other findings within the same study." Dec. at 150.

Having considered Petitioners' expert witnesses, the Special Master proceeded to apply the three-part test articulated in *Althen*, 418 F.3d at 1278. Dec. at 157. *Althen* requires a petitioner in an off-Table causation case to provide: "a medical theory causally connecting the vaccination and injury; a logical sequence of cause and effect . . . ; and . . . a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

For the first *Althen* element, the Special Master found that while "[m]itochondrial autism" may someday be accepted as a descriptor for co-morbid autism and mitochondrial disorder

diagnoses . . . there is little evidence that autism itself is caused by such disorder, and no evidence that autism causes mitochondrial disorders.” Dec. at 157. The Special Master also found that Dr. Kendall’s theory is “completely unsupported by any scientific literature.” Dec. at 157. Moreover, Dr. Shafrir “failed to articulate any basis for claiming that an influenza vaccination could lead, via autoimmunity, to the type of injury A.K. experienced.” Dec. at 157. In addition, the Special Master found that “Doctor Deth’s opinion suffered far too many serious flaws to be credited.” Dec. at 158. Here, the Special Master noted that “Dr. Deth acknowledged that not all oxidative stress is injurious . . . [and] conceded that he could not opine what level of oxidative stress is created by a vaccination or what level of oxidative stress would be necessary to cause the type of neurological injury he described.” Dec. at 158.

For the second and third *Althen* elements, the Special Master found that there was not a logical sequence of cause and effect between the vaccination and injury or proximate temporal connection, because “there is strong evidence in the record suggesting that A.K.’s condition predated his vaccinations.” Dec. at 158.

E. Petitioners’ October 28, 2015 Motion For Review.

1. Petitioners’ Objections.

Petitioners’ October 20, 2015 Motion includes a constitutional claim and twelve objections to the Special Master’s September 28, 2015 Decision that are summarized as follows: 1) the amendment of the Vaccine Act is unconstitutional; 2) the Special Master’s determination that A.K.’s ASD predated the influenza vaccinations was arbitrary and capricious; 3) the Special Master’s determination that A.K. did not have an underlying mitochondrial disorder was arbitrary and capricious; 4) the Special Master misapplied *Althen* to Petitioners’ causation theories; 5) the Special Master improperly denied Petitioners’ Motion For Judicial Estoppel; and 6) the Special Master improperly denied Petitioners’ Motion To Exclude.

Petitioners first argue that Congress cannot bar common law litigants from access to Article III courts. Pet. Mem. at 3 (citing *Stern v. Marshall*, 131 S. Ct. 2594, 2615 (2011) (“The ‘experts’ in the federal system at resolving common law counterclaims . . . are the Article III courts[.]”). Because the Vaccine Act denies Petitioners access to an Article III court, the Vaccine Act is unconstitutional and denies due process of law. Pet. Mem. at 3.

The Special Master’s determination that A.K.’s ASD predated the influenza vaccinations also was arbitrary and capricious, because the Special Master credited the Government’s expert witness, Dr. Miller, over Petitioners’ expert witness, Dr. Boris, who had “a far greater level of experience than Dr. Miller and had the advantage of treating [A.K.] over a long period of time[.]” Pet. Mem. at 7–8. Dr. Megson also was more qualified than Dr. Miller, because she is “a developmental pediatrician with over 40 years’ experience specializing in the treatment of autistic children, with the added qualification of being the mother of four children, three of whom are boys[.]” Pet. Mem. at 12. Because the Special Master relied on Dr. Miller instead of Petitioners’

superior expert witnesses, the Special Master's conclusion was "unsupported by competent evidence." Pet. Mem. at 15.

Next, Petitioners contend that the Special Master's "conclusion that [A.K.] does not have mitochondrial disease is one that defies applicable law." Pet. Mem. at 17. Mitochondrial disorder diagnosis lacks an objective diagnostic criteria. Pet. Mem. at 19. When "reasonable medical minds may legitimately differ . . . [the United States Court of Appeals for] [t]he Federal Circuit's instruction set forth in *Althen*, 418 F.3d 1274 (Fed. Cir. 2005) and *Capizanno*, 440 F.3d 1317, 1325 (Fed. Cir. 2006) . . . is to defer to the petitioners' experts[.]" Pet. Mem. at 19.

In addition, the Special Master's conclusion that Petitioners did not provide a reliable causation theory was error and the Special Master improperly raised Petitioners' burden of proof. Pet. Mem. at 33, 38. In determining that the Petitioners' experts did not establish how or why a fever can cause oxidative damage in conjunction with mitochondrial disease, the Special Master improperly raised the burden of proof to beyond a preponderance of evidence standard. Pet. Mem. at 39.

Petitioners add that the Special Master erred in denying Petitioners' Motion to estop the Government from denying that a vaccination creates sufficient stress to cause autism in a child with mitochondrial disorder. Pet. Mem. at 56. Specifically, in *Poling*, 2008 WL 1883059, the Government filed a Rule 4 Report, conceding that "the facts of this case meet the statutory criteria for demonstrating that the vaccination . . . received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder, which . . . manifested as a regressive encephalopathy with features of [ASD]." *Poling*, 2008 WL 1883059, at *1. Therefore, the Government should have been estopped from arguing otherwise here. Pet. Mem. at 57.

Finally, the Special Master's denial of Petitioner's Motion To Exclude The Testimony Of Dr. Miller⁸ was in error. Pet. Mem. at 57.

2. The Government's Response.

The Government did not respond to Petitioners' constitutional argument; but defended the Special Master's determination that A.K.'s ASD predated the influenza vaccination was not arbitrary or capricious. Gov't Mem. at 12. It is within a Special Master's purview to weigh expert testimony. Gov't Mem. at 13 (citing *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1325 (Fed. Cir. 2010) ("Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and we have made clear that the [S]pecial [M]asters have that responsibility in Vaccine Act cases.")). The Special Master's decision that Dr. Miller was more credible than Petitioners' experts is supported by evidence. Gov't Mem. at 13. Dr. Miller has more publications on ASD than Petitioners' experts. Gov't Mem. at 13. Dr. Miller also has experience diagnosing ASD, as well as teaching others how to diagnose ASD. Gov't Mem. at 13. Moreover, "the Special Master was clear that while she afforded Dr. Miller's opinion substantial weight, her determination was based on the totality of evidence[.]" Gov't Mem. at 15. "The Special Master also pointed out that two of petitioners'

⁸ Here, Petitioners refer to the Motion To Strike addressed in the Special Master's Ruling On Motions. See Ruling, No. 030632V, at 48–49 (considering Petitioners' argument "that Dr. Miller's testimony should be stricken in its entirety" as a "Motion [T]o Strike Dr. Miller's Testimony").

experts, Dr. Megson and Dr. Kendall essentially confirmed that A.K. showed symptoms of his ASD months before vaccinations.” Gov’t Mem. at 15 (citing Dec. at 79, 88).

The Government argues that the Special Master “did not err in finding that A.K. does not have a mitochondrial disorder[,]” because the Special Master’s determination is supported by the record. Gov’t Mem. at 19. The Special Master found Dr. Kendall’s testimony unreliable, because Dr. Kendall, when cross examined, did not defend her position that A.K. definitively had mitochondrial dysfunction. Gov’t Mem. at 21. The Special Master evaluated and analyzed the evidence under the Bernier criteria and is reasoned and factually supported. Gov’t Mem. at 21.

In addition, Petitioners’ reading of *Althen* and *Capizanno* is incorrect. Gov’t Mem. at 23. The Special Master is not required to defer to any of the experts nor notations in the record. Gov’t Mem. at 23. Instead, “it was her duty to evaluate the entire evidentiary record, make findings of a fact, and reach a conclusion . . . in light of the record as a whole.” Gov’t Mem. at 23 (citing *Sword v. Sec’y of Health & Human Servs.*, 44 Fed. Cl. 183, 188 (1999) (“Expert opinion is just opinion, and the fact-finder may weigh and assess that opinion in coming to her own conclusions. . . . [T]his [c]ourt has recognized the unique ability of Special Masters to adjudge cases in light of their own acquired specialized knowledge and expertise[.]”).

Likewise, the Special Master’s determination that Petitioners’ causation theories were unreliable was in accordance with the law. Gov’t Mem. at 24. The Special Master thoroughly evaluated, but rejected two pieces of evidence on which Dr. Kendall relied to support her causation theory. Gov’t Mem. at 26. The Special Master also properly rejected the *Poling* case study and Dr. Shoffner’s article. Gov’t Mem. at 26. The Special Master’s determination that Petitioners’ expert witness, Dr. Deth, was not credible is “wholly within the Special Master’s charge.” Gov’t Mem. at 29 (citing *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000) (stating that a Special Master’s “assessments of the credibility of witnesses and the relative persuasiveness of the competing medical theories of the case . . . are virtually unchallengeable on appeal[.]”).

The Special Master also correctly denied Petitioners’ Motion For Estoppel and Motion To Exclude.⁹ Gov’t Mot. at 33. In the Ruling On Motions, the Special Master provided four reasons for rejecting judicial estoppel:

- (1) Judicial estoppel does not apply when a case has been settled;
- (2) petitioners failed to satisfy the three requirements for the invocation of judicial estoppel;
- (3) decisions issued by special masters and judges at the [United States] Court of Federal Claims are not binding; and
- (4) a concession by respondent in one case does not constitute a concession in another.

Gov’t Mem. at 33 (citing Ruling at 36–37).

⁹ The Government collectively refers to these motions as a Motion To Strike as addressed in the Special Master’s Ruling On Motions. See Ruling at 48–49 (interpreting Petitioners’ argument “that Dr. Miller’s testimony should be stricken in its entirety” as a “Motion [T]o Strike Dr. Miller’s Testimony”).

With respect to Petitioners' Motion To Exclude, the Special Master found Dr. Miller qualified to testify, but "noted that any deficiencies in . . . Dr. Miller's testimony 'are more appropriately addressed in the assignment of weight to her testimony rather than its wholesale exclusion.'" Gov't Mem. at 33–34 (quoting Ruling at 54).

3. The Court's Resolution.

a. The Constitutional Issue.

As a threshold matter, the Vaccine Act is constitutional, because the Vaccine Act categorically does not deny access to Article III courts. In fact, Petitioners may appeal this decision to the United States Court of Appeals for the Federal Circuit. *See* 42 U.S.C. § 300aa-12(f) ("[A]ny petitioner aggrieved by the findings or conclusions of the [United States Court of Federal Claims] may obtain review of the judgment of the court in the United States Court of Appeals for the Federal Circuit[.]"). In addition, Petitioners have misread *Stern*'s holding that Article I bankruptcy courts do not have jurisdiction over common law claims between *private* parties. *See Stern*, 131 S. Ct. at 2614–15 (recognizing that the claim at issue was "one under state common law between two private parties. . . . The 'experts' in the federal system at resolving common law counterclaims . . . are the Article III courts[.]"). The claims in this case, are alleged against the Government rather than a private party. Moreover, *Stern* has been limited by the United States Supreme Court's recent decision in *Wellness Int'l Network, Ltd. v. Sharif*, 135 S. Ct. 1932, 1944 (2015) that held, "allowing Article I adjudicators to decide claims submitted to them by consent does not offend the separation of powers so long as Article III courts retain supervisory authority over the process."

b. The Merits.

As for the Special Master's causation determination, the first element of *Althen* requires "a medical theory causally connecting the vaccination and the injury[.]" *Id.* at 1278. The Special Master found that Petitioners did not satisfy the first element in concluding that Dr. Kendall's causation theory was "unsupported by any scientific literature." Dec. at 157. The United States Court of Appeals for the Federal Circuit has held that requiring general acceptance by the scientific community or requiring medical literature impermissibly raises the preponderance of the evidence standard. *See Althen*, 418 F.3d at 1281 ("[T]he Vaccine Act does not require Althen [the petitioner] to provide medical documentation of plausibility[.]").

The second element requires "a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]" *Id.* at 1278. The third element requires "a proximate temporal relationship[.]" *Id.* Here, the Special Master properly determined that Petitioners failed to establish the second and third elements, because A.K. showed "signs of both ASD and speech delay well before receiving . . . influenza vaccinations." Dec. at 158. Therefore, the Special Master determined that there was not a logical sequence, because "the actual timeline of events do not support [P]etitioners' claim of a regression." Dec. at 158. Although the Special Master misapplied the first element, the correct application of the second and third elements is dispositive as to causation.

The Special Master's determination that A.K.'s ASD predated the influenza vaccinations was not arbitrary and capricious. It is clear from the September 28, 2015 Decision that the Special Master based findings of fact about this issue by weighing the credibility of both parties' experts,

analyzing medical records and related evidence, and personally viewing the home videos of A.K. Dec. at 68–96.

Likewise, the Special Master’s determination that A.K. did not have an underlying mitochondrial disorder is not arbitrary and capricious, because as the fact-finder, the Special Master may assess “the credibility of the witnesses and the relative persuasiveness of the competing medical theories of the case.” *Lampe*, 219 F.3d at 1362.

As to this issue, Petitioners had the burden to establish that A.K. had a mitochondrial disorder, but as the Special Master’s decision states, did not meet a preponderance of evidence standard. *See Althen*, 418 F.3d at 1278 (“[Petitioner] sought redress . . . for off-Table injury. [Petitioner] must prove by a preponderance of the evidence that the [] vaccination caused her malady.”); *see also Capizanno*, 440 F.3d at 1320 (“In [an off-Table injury] case, the petitioner must prove by a preponderance of the evidence that the vaccine at issue caused the injury.”). In this case, the Special Master carefully considered the testimony of Petitioners’ expert, Dr. Kendall. Dec. at 49. In addition, the Special Master took into consideration that, on cross examination, Dr. Kendall contradicted her report by conceding that she could not conclude that A.K. definitively had mitochondrial disorder. 4/22/2013 TR 319. The Special Master also examined A.K.’s lab results and medical literature proffered. Dec. at 54–68. Therefore, the Special Master “considered the relevant evidence of record, [drew] plausible inferences, and articulated a rational basis for the decision.” *Lampe*, 219 F. 3d at 1360 (internal quotations omitted). As such, it is not for the court “to reweigh the factual evidence, or to assess whether the [S]pecial [M]aster correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder.” *Munn*, 970 F.2d at 871.

c. Judicial Estoppel.

Judicial estoppel “generally prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase.” *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) (internal quotations omitted). Three factors inform whether judicial estoppel applies:

[A] party’s later position must be ‘clearly inconsistent’ with its earlier position Second, courts regularly inquire whether the party has succeeded in persuading a court to accept that party’s earlier position Absent success in a prior proceeding, a party’s later inconsistent position introduces no ‘risk of inconsistent court determinations. . . . A third consideration is whether the party seeking to assert an inconsistent position would derive an unfair advantage[.]

Id. at 750–51 (internal citations omitted).

In the September 28, 2015 Ruling On Motions, the Special Master applied the *New Hampshire* factors in denying Petitioners’ Motion For Judicial Estoppel. First, the Special Master determined that the Government’s position in this case was “not ‘clearly inconsistent’” with its position in *Poling*. Ruling at 36. “In *Poling*, [the Government’s] position was that the child had sustained a Table injury . . . and thus presumptively should be compensated. Here, there is no allegation that A.K. suffered a Table injury within the requisite time period.” Ruling at 36. The Special Master also determined that there was no risk of inconsistent court determinations, because

“Special [M]asters are neither bound by their own decisions nor by cases from the [United States] Court of Federal Claims, except, of course, in the same case on remand.” Ruling at 36. Finally, the Special Master determined that Petitioners were not at an unfair disadvantage, because the Government’s position in *Poling* and this case are not inconsistent. Ruling at 37.

Specifically, in *Poling*, the “vaccinations Hannah received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of [ASD].” Rule 4(c) Report at 7, *Poling ex rel. Poling v. Sec’y of Health & Human Servs.*, No. 02-1466 V, 2008 WL 1883059 (Fed. Cl. Spec. Mstr. Apr. 10, 2008). The vaccinations at issue there were DTaP, Hib, MMR, Varivax, and IPV. Rule 4(c) Report at 2, *Poling ex rel. Poling v. Sec’y of Health & Human Servs.*, No. 02-1466 V, 2008 WL 1883059 (Fed. Cl. Spec. Mstr. Apr. 10, 2008). But the vaccinations in this case are influenza vaccinations. As such, the Government did not assert an inconsistent position that triggers judicial estoppel.

d. Abuse Of Discretion.

With respect to the Special Master’s denial of Petitioner’s Motion To Exclude Dr. Miller’s Testimony, the court applies an abuse of discretion standard. *See Munn*, 970 F.2d at 870 n.10 (“[D]iscretionary rulings [are reviewed] under the abuse of discretion standard. The latter will rarely come into play except where the [S]pecial [M]aster excludes evidence.”). To find an abuse of discretion, the court must determine that the Special Master’s decision was “(1) . . . clearly unreasonable, arbitrary, or fanciful; (2) . . . based on an erroneous conclusion of the law; (3) . . . clearly erroneous; or (4) the record contains no evidence on which the . . . [Special Master] rationally could have based his decision.” *Hendler v. United States*, 952 F.2d 1364, 1380 (Fed. Cir. 1991). An abuse of discretion generally does not occur where a Special Master “considered the relevant evidence, drew plausible inferences, and articulated a rational basis for his finding[.]” *Masias v. Sec’y of Health & Human Servs.*, 634 F.3d 1283, 1290 (Fed. Cir. 2011).

The Special Master in this case considered Dr. Miller’s experience at the Children’s Hospital of Philadelphia in the Center for Autism Research. 4/25/2013 TR 847. The Special Master also considered the Government’s other witness, Dr. Bruce Cohen, who corroborated Dr. Miller’s testimony. Ruling at 54. In addition, the Special Master found that Dr. Miller had “more publications on the topic of ASD than any of [P]etitioners’ own experts.” Ruling at 54. Therefore, since the Special Master’s decision was supported, there was no abuse of discretion.

IV. CONCLUSION.

For the reasons discussed, the court denies Petitioners’ October 28, 2015 Motion For Review. The Clerk of the Court is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Susan G. Braden
SUSAN G. BRADEN
Judge

