IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

No. 11-141V
Filed: March 26, 2015

RAMANATHAN PADMANABHAN and KRITHIKA SRINIVAS, legal representatives of a minor child, I.R.I., Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	Motion to Suspend Proceedings; Failure to Prosecute; Failure to Comply with Court Orders; Insufficient Evidence of Causation; Autism; Mitochondrial or Metabolic Disorder

DISMISSAL DECISION[1] AND RULING ON MOTION TO SUSPEND PROCEEDINGS

Vowell, Chief Special Master:

On March 7, 2011, Ramanathan Padmanabhan and Krithika Srinivas ["Mr. Padmanabhan," "Ms. Srinivas," or "petitioners"], acting *pro se*, timely filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq*.[2] [the "Vaccine Act" or "Program"], on behalf of their minor son, I.R.I. The petition alleged that the measles, mumps, and rubella ["MMR"], diphtheria, tetanus, and acellular pertussis ["DTaP"], Haemophilus influenzae type b ["Hib"], and varicella vaccines that I.R.I. received on or about March 13, 2008 "significantly aggravated a

[1] Because this decision contains a reasoned explanation for my action in this case, it will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa.

preexisting [m]itochondrial disease," and that he "suffered injuries caused by one or a combination of the eight vaccines given to him" on that day. Petition, ¶¶ 1, 38.

In the four years since the petition was filed, petitioners have repeatedly refused to file complete medical records as required by § 11(c)(2) and Vaccine Rule 2(c). Petitioners insist that the records they have provided establish entitlement to compensation. These incomplete medical records reflect that I.R.I. has an autism spectrum disorder ["ASD"] diagnosis.[3] Petitioners' Exhibits ["Pet. Exs."] 1, p. 91; 10, pp. 338-49. An ASD diagnosis does not preclude the presence of co-morbid conditions such as mitochondrial or metabolic disorders, but petitioners have not provided evidence that I.R.I. has been so diagnosed. Specifically, the filed medical records do not reflect any qualified physician's diagnosis of a mitochondrial disorder, despite petitioners' claims. There is laboratory evidence that I.R.I may have a short chain acylCoA dehydrogenase ["SCAD"] deficiency, but no physician's diagnosis of such a condition appears in the records.[4] Ultimately, even if petitioners' claims regarding I.R.I.'s diagnoses are accurate, the evidence is inadequate to demonstrate vaccine causation.

For the reasons set forth below, I dismiss their petition for failure to comply with court orders and failure to prosecute. Alternatively, I treat their assertions that they have established a prima facie case for entitlement to compensation (*see* Petitioners' Motion, filed Aug. 16, 2013, at 2; *see also* Petitioners' Post-Argument Filing at 4) as either a motion for summary judgment or a request that I rule on the record as it stands. Based on any of their theories, the record does not contain preponderant evidence establishing their entitlement to compensation.

I. Procedural History.

This case has a somewhat unusual procedural history. Shortly after the petition was filed, the former Chief Special Master transferred the case to me.[5] Petitioners

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[3] "A diagnosis of autistic disorder requires a minimum of six findings from a list of impairments divided into three domains of impaired function: (1) social interaction; (2) communication; and (3) restricted, repetitive, and stereotyped patterns of behavior, interests, and activities. At least two findings related to social interaction and at least one each in the other two domains are required for diagnosis. To meet the diagnostic criteria for autism, the child must have symptoms consistent with six of the twelve listed types of behavioral impairments. Furthermore, the abnormalities in development must have occurred before the age of three." *White v. Sec'y, HHS,* No. 04-337V, 2011 WL 6176064, at *6 (Fed. Cl. Spec. Mstr. Nov. 22, 2011). These diagnostic criteria are drawn from the Diagnostic and Statistical Manual IV-TR, the manual used to diagnose ASD in effect at the time of I.R.I.'s diagnosis.

[4] A SCAD deficiency is a fatty acid oxidation disorder (an inborn error of metabolism). It is explained in more detail in Section IV.B.2 below.

[5] Upon reassignment of the case to me, I conducted a lengthy initial status conference followed by an initial order. After petitioners requested clarification of the reassignment, I issued an order explaining the

questioned the reassignment of their case and ultimately sought judicial review of the reassignment, as well as review of the use of an internal "flag" on the Court's electronic docket.[6]

The matter was assigned to Judge Mary Ellen Coster Williams, who concluded that the Court of Federal Claims lacked jurisdiction to review matters unrelated to "compensation for injuries or attorneys' fees under the Vaccine Act." Memorandum Opinion and Order Dismissing Motion for Review, filed Sept. 15, 2011, at 3. I then began what has proved to be a futile effort to obtain a complete record of I.R.I.'s medical treatment. *See, e.g.*, Order, issued Oct. 11, 2011. Although petitioners filed some medical records with their petition on March 7, 2011, and some additional records on June 13, 2011, December 8, 2011, and August 16, 2013, the medical records remain incomplete.

In the four years since filing this petition on their son's behalf, petitioners have refused to comply with numerous orders. They have refused to follow the Vaccine Rules regarding the filing of motions. They have repeatedly requested that proceedings in their case be suspended and have twice demanded that I recuse myself because of my opinions in the Omnibus Autism Proceeding cases.[7] They have alleged a conspiracy by the "vaccine ecosystem" to deny them compensation (*see* Petitioners' Response to Order to Show Cause, filed Jan. 17, 2014, at 4), and have repeatedly asserted that the incomplete medical records and other documents filed, which do not include any expert's or treating physician's opinion regarding vaccine causation of I.R.I.'s condition, demonstrate entitlement to compensation. *See, e.g.,* Pet. Motion, filed Aug. 16, 2013, at 2; Pet. Post-Argument Filing at 4. In a display of remarkable obstinacy, they have also refused to file additional medical records, despite my repeated orders. Because the medical records on file are insufficient to establish either the diagnoses claimed or causation on the theories presented, and my efforts to convince petitioners to complete the record have been unavailing, a report by respondent pursuant to Vaccine Rule 4 was never ordered. I.R.I.'s case has essentially been at an impasse since December 2012.

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transfer and held another telephonic status conference to address petitioners' concerns. Order, issued Apr. 25, 2011.

[6] During the initial status conference, petitioners claimed that they had not received a copy of the reassignment order. Petitioners became aware of this "flag," a mechanism used by court personnel to track case status for docket management purposes, when a printed copy of the docket sheet was sent to them to establish that the reassignment order had been filed. *See* Order, issued May 12, 2011, at 2.

[7] The Omnibus Autism Proceeding ["OAP"] is discussed in detail in *Dwyer v. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250, at *3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). In both of my test case decisions (one on each of the two theories of causation presented), I found inadequate evidence that vaccines cause autism spectrum disorders. Decisions in other cases do not constitute a basis for recusal. *See, e.g., Liteky v. U.S.,* 510 U.S. 540, 551 (1994) ("opinions held by judges as a result of what they learned in earlier proceedings" do not constitute bias or prejudice).

In the spring of 2012, petitioners first requested that proceedings in their case be suspended. Pursuant to § 12(d)(3)(C), I suspended proceedings for 30 days. After they filed a request explaining why a longer suspension was necessary, I suspended the proceedings for an additional 150 days. *See* Order, issued Mar. 22, 2012; Pet. Motion for Extension of Time, filed May 24, 2012; Order, issued May 25, 2012; Pet. Motion to Suspend Proceedings, filed Jul. 2, 2012; Order, issued Jul. 11, 2012. This 180-day suspension is the maximum period authorized by the Vaccine Act. § 12(d)(3)(C).

Following this suspension of proceedings, respondent filed a status report listing important medical records that had not been filed. Specifically, respondent requested (1) I.R.I.'s prenatal and birth records; (2) results of the muscle biopsy, brain MRI, and other mitochondrial and metabolic testing recommended by Dr. Richard Haas at I.R.I.'s October 19, 2010 appointment; and (3) I.R.I.'s relevant treatment records from 2012 to the present.[8] *See* Status Report, filed Dec. 14, 2012. On December 18, 2012, I ordered petitioners to file these records or otherwise explain their absence. *See* Order, issued Dec. 18, 2012.

After failing to comply with this order and two additional orders filed Feb. 7, 2013, and Feb. 28, 2013, petitioners filed a status report indicating that they did not "have possession of the records asked as those tests have not been performed on the advise [*sic*] of treating physicians." Petitioners asserted that their son has been diagnosed with mitochondrial and metabolic disorders and that "those records are already on file." Petitioners also indicated that birth and prenatal records had been filed. Pet. Status Report, filed Mar. 7, 2013, at 3.

Shortly thereafter, I issued a detailed order explaining the deficiencies in the medical records and petitioners' obligation to file all recent medical and treatment records. Order, issued Mar. 12, 2013. I instructed petitioners to file by May 13, 2013: (1) I.R.I.'s prenatal and birth records and (2) medical treatment records of I.R.I. from October 2011 forward. Order, issued Mar. 12, 2013, at 4.

Once more, petitioners failed to comply with my order. After an Order to Show Cause was issued on May 13, 2013, petitioners filed I.R.I.'s complete prenatal and birth records, but not his recent treatment records. Petitioners also moved to suspend proceedings, to be given more time to file updated records, and for recusal. Motion, filed Aug. 16, 2013. I denied petitioners' motions and again ordered petitioners to file medical records from all providers who had seen or treated I.R.I. since October 2011.

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[8] It appears that other medical treatment records may be missing as well. For instance, while several laboratory test results ordered by Dr. Bryan Jepson have been filed, none of his notes, diagnoses, or office visit logs are part of the record. *See* Pet. Ex. 4. No records pertaining to I.R.I.'s speech, occupational or behavioral therapy were filed. However, these and other missing medical treatment records do not appear as central to petitioners' theory as those requested by respondent, as those records are likely to contain evidence of further testing, diagnoses, and opinions by treating physicians.

Order, issued Sept. 26, 2013. I also addressed petitioners' concerns that their son's treatment could be jeopardized by asking his physicians to opine on I.R.I.'s case, noting that petitioners had only been ordered to file records pertaining to medical treatment, not opinions on causation. *Id.* at 4.[9] Finally, I once again explained that the medical records on file were "insufficient to establish entitlement to compensation." *Id.*

Petitioners again failed to comply with my order. On November 15, 2013, I issued an order in which I noted that dismissal for failure to prosecute appeared warranted, but I would give petitioners "one last chance to comply with my orders and establish they are entitled to compensation because the interests of a minor child are involved." Order, issued Nov. 15, 2013 at 2. I carefully explained petitioners' burden of proof under *Althen* and its progeny and reminded petitioners that a finding of entitlement to compensation must be supported by medical records or the opinion of a medical expert. *Id.* at 3. I ordered petitioners to file "any additional documentation they believe will establish their entitlement to compensation, or otherwise show cause why this case should not be dismissed for their failure to prosecute and failure to establish vaccine causation" by January 17, 2014. *Id.* at 4.

On November 21, 2013, petitioners contacted my law clerk and informally requested that proceedings in this case be suspended for six months. In response, I issued an order in which I explained that I would not act on an informal request and reiterated that any motion must be filed with the clerk of court. Order, issued Nov. 25, 2013. I explained the difference between a law clerk and a court clerk and why petitioners must file documents and requests formally with the Clerk of Court, not informally with my chambers staff. I ordered petitioners to comply with my prior orders by January 17, 2014. *Id.* I also informed petitioners that I had instructed my law clerk to disregard any email from them that did not pertain to administrative questions.

A few weeks later, on December 4, 2013, petitioners emailed my law clerk and again requested a suspension of proceedings. My law clerk reminded petitioners that they must bring all substantive matters to my attention in formal filings and directed them to my previous orders.

On January 2, 2013, petitioners again emailed my law clerk. My law clerk directed petitioners to my November 25, 2013 order and reiterated that all motions must be officially filed with the Court. Petitioners responded with other informal communications.

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[9] The CM/ECF scanned copy of this Order is missing two pages of the original order. However, the paper record is the official record in this case because petitioners are *pro se* litigants. *See* numbered paragraph 3 of the Supplement to Appendix B, Electronic Filing Procedure in Vaccine Act Cases. To avoid confusion, the Clerk's Office has been ordered to rescan and post a complete copy of the order.

In one more effort to explain why petitioners were required to file documents in accordance with the Vaccine Rules, an ability they had demonstrated, I restated and summarized the guidance given in my previous orders. *See* Order, issued Jan. 8, 2014. I gave detailed instructions about filing requirements and explained the role of status conferences. I reminded petitioners that they had not provided any evidence that producing the records required would actually affect the doctor-patient relationship or their son's treatment. I noted that if such evidence existed, I could conduct an *in camera* review of any material they deemed sensitive. *Id.* at 5.

I also explained to petitioners once again that the medical records on file were not sufficient to prove causation. I informed them that they had not advanced a medical theory explaining how vaccines can significantly aggravate mitochondrial disorders, nor had they filed any medical records indicating their son has been diagnosed with a mitochondrial disorder or a SCAD deficiency. I again urged petitioners to retain counsel and directed them once more to a list of attorneys with experience representing petitioners in the Vaccine Program.[10] Finally, I informed petitioners that they were required to comply with my prior orders to file "any additional documentation they believe will establish their entitlement to compensation, or otherwise show cause why this case should not be dismissed" no later than January 17, 2014. Order, issued Jan. 8, 2014, at 7.

On January 17, 2014, petitioners filed another motion to suspend proceedings, requested a status conference, and made a discovery request. Despite my numerous warnings about the consequences of their failure to comply with my orders, petitioners again failed to file any medical records with their motion. On March 28, 2014, I denied petitioners' motions and made "one final attempt to explain to petitioners the devastating effect that their refusal to comply with court orders is about to have on their son's vaccine injury claim." Order, issued Mar. 28, 2014.

I also noted that petitioners' January 17, 2014 filing appeared to allege that I.R.I. suffered a Table[11] encephalopathy as a result of his vaccines, a claim not expressly made in their petition or in any of their other filings. I informed petitioners that the medical evidence filed was insufficient to support a Table encephalopathy claim. Order, issued Mar. 28, 2014, at 2. I explained the requirements for petitioners to be successful on either a causation-in-fact encephalopathy claim or under a significant aggravation theory. I also reminded petitioners that they had not produced evidence supporting a significant aggravation injury claim. *Id.* at 2-4.

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[10] Given that the Program will pay reasonable attorney fees and costs for most unsuccessful litigants (§300aa-15(e)(1); *Sec'y, HHS v. Cloer,* 133 S.Ct. 1886 (2013)), it is unclear why petitioners have not actively pursued, or have been unsuccessful in obtaining, representation.

[11] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified. The more specific requirements for a Table encephalopathy are set forth in Section V.B.2 below.

This March 28, 2014 order also addressed petitioners' concerns about potential intimidation of I.R.I.'s medical care providers. I noted that Mr. Padmanabhan's assertions regarding efforts to coerce or intimidate doctors treating his son had not been accompanied by any evidence. I once again provided petitioners with the opportunity to send any evidence of impropriety directly to the court for my *in camera* review. Order, issued Mar. 28, 2014, at 6. I explained that the filing of medical records is routine in vaccine injury cases. I provided information about how to request their son's records via the websites of several facilities where I.R.I. received treatment. *Id.*

Because petitioners alleged that I had not reviewed "the entire record and relevant research," I pointed out that petitioners had not filed any relevant research[12] and explained the proper procedure for filing research and articles. I reiterated that I had not ordered and was not now ordering petitioners to file medical journal articles, but reminded petitioners that they could file any article they felt was relevant. I attached four articles that I have reviewed in previous vaccine cases that appeared relevant to petitioners' claims as Court Exhibits I-IV. Order, issued Mar. 28, 2014, at 7.

Regarding petitioners' request for a status conference, I explained that periodic status conferences are designed to "expedite the processing of the case." Vaccine Rule 6(a). I noted that a status conference would serve no useful purpose in this case until petitioners clarified their theory of causation and filed updated medical records.[13] I reiterated that I would schedule a status conference after petitioners had filed the missing records or produced evidence of intimidation. Order, issued Mar. 28, 2014, at 7-8.

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[12] The only "research" filed by petitioners in this case consists of a number of abstracts from medical journals contained in Pet. Ex. 12 and one journal article, Pet. Ex. 15, C. Pedersen, *et al., The ACADS gene variation spectrum in 114 patients with short-chain acyl-CoA dehydrogenase (SCAD) deficiency is dominated by missense variations leading to protein misfolding at the cellular leve*l, HUMAN GENETICS, 124(43) (2008) [hereinafter "Pederson, Pet. Ex. 15"]. (A supplementary table accompanying the article was filed as Petitioners' Exhibit 16.) This article does not address how vaccines could cause, exacerbate, or interact with a SCAD deficiency in order to cause symptoms of an ASD. The abstracts in Pet. Ex. 12 (the pages of which are unnumbered) do not discuss mitochondrial disorders, SCAD deficiency, or autism. Most of the abstracts describe research on hearing loss and environmental toxicity. Petitioners' January 17, 2014 response to an order to show cause included hyperlinks to several medical journal articles. In my March 28, 2014 order, I explained that these articles were not properly filed and gave them instructions on how to file them. I also noted that I had read the journal articles and that none of them addressed the impact of vaccines on a person with SCAD. The articles were never filed.

[13] Petitioners have proven to be remarkably combative during status conferences, which have frequently lasted more than an hour and achieved very little, other than allowing Mr. Padmanabhan to make unsubstantiated allegations and reiterate that he was entitled to compensation. *See, e.g.,* status conferences held Mar. 21, 2012 (02:05-03:06 PM EST); Oct. 5, 2011 (02:01-03:09 PM EST); May 11, 2011 (01:01-02:09 PM EST).

Finally, I laid out options for petitioners. I noted that they could ask me to rule on the record as it now stands or request summary judgment, although I urged them to seek an attorney before doing so. I provided petitioners with a list of attorneys who had indicated a willingness to review cases filed by *pro se* petitioners. I ordered petitioners to file either an amended petition or a causation statement setting forth their theory or theories of vaccine causation by April 28, 2014. I also ordered petitioners to file by May 27, 2014, updated medical records, including all doctor appointments and testing performed since October 2011. Order, issued Mar. 28, 2014, at 8.

Petitioners filed nothing in response to my order. Nevertheless, prior to taking any further action, I afforded them the opportunity to point out in a telephonic conference any matters in the record that support their claim of vaccine causation of I.R.I.'s condition. Order, issued Jun. 4, 2014. I held this telephonic conference on July 23, 2014. Following the conference, petitioners requested the opportunity to address in writing the cases cited by respondent during the conference once the transcript of the proceedings was available. *See* Orders filed Jul. 25, 2014, and Aug. 18, 2014. On October 1, 2014, petitioners filed their response, which included one more motion to suspend proceedings. Respondent filed her reply on October 16, 2014.

The evidentiary record remains incomplete due to petitioners' refusal to file records pertaining to I.R.I.'s diagnoses and treatment. Nevertheless, it is the record upon which I now must decide this case.

Petitioners' latest motion to suspend the proceedings is denied for the reasons set forth in Section II. Further, petitioners have repeatedly refused to comply with my orders and their intractability on this issue leaves me no reason to expect that they will ever complete the record. Failure to follow court orders, as well as failure to file medical records or an expert medical opinion, is ground for dismissal. Their case is thus dismissed for failure to prosecute for the reasons set forth in Section III.

Alternatively, treating petitioners' assertions that the record establishes entitlement to compensation as either a motion for summary judgment or a motion for a ruling on the record, their case is likewise dismissed for the reasons set forth in Section IV.

II. Petitioners' Motion to Suspend Proceedings.

In March 2012, petitioners first requested that I suspend further proceedings in this case. I granted their request, giving them first a 30-day suspension and, once a justification for additional time was filed, granting a further 150-day suspension period. Since that time, petitioners have made five requests, formal and informal, for additional suspensions. I denied each of the formal requests, pointing out that the Vaccine Act

authorizes the special master to grant a suspension of proceedings for only 180 days.[14] As indicated above, I have not ruled on any of their informal requests.

On September 30, 2014, petitioners moved once again to suspend proceedings, arguing that a pending Congressional investigation could "impact the outcome of [their] petition." Pet. Mot. to Suspend Proceeding [hereinafter "Pet. Mot. Sept. 30"], at 1. They alleged "substantial harm if [their] petition is decided by Office of Special masters [*sic*] without waiting for complete evidence that has come to light." Pet. Mot. Sept. 30 at 1. Their motion included a statement that a "senior researcher" at the Centers for Disease Control and Prevention ("CDC") admitted to tampering with data that showed a positive link between the MMR vaccine and autism in male, African-American children. Pet. Mot. Sept. 30 at 1-2. Arguing that the CDC is an "operating arm" of the respondent, petitioners contended that a denial of their motion to suspend proceedings would unjustly prejudice petitioners because of an intentionally dishonest action by the respondent herself. *See* Pet. Mot. Sept. 30 at 1, 3. Petitioners asserted that this unidentified[15] and allegedly fraudulent article substantially affected my decision in the OAP test case regarding the measles theory. *See* Pet. Mot. Sept. 30 at 1-2.

In her reply, respondent claimed she was unaware of any Congressional investigation, and furthermore, stated that petitioners "have not offered any evidence of a pending Congressional investigation that impacts their case in any way." Reply to Petitioners' Post-Argument Filing [hereinafter "Res. Reply Oct. 16"] at 5. Respondent further incorporated her past responses to petitioners' motions to suspend proceedings. Res. Reply Oct. 16 at 4; *see also* Respondent's Response to Petitioners' Response to Order to Show Cause (Jan. 29, 2014); Response to Petitioners' Motion (Sept. 3, 2013); Respondent's Response to Petitioners' Motion to Suspend Proceedings, July 10, 2012; Respondent's Response to Petitioners' Motion to Correct the Record (Dec. 20, 2011). She argued that, under Vaccine Rule 9, petitioners are entitled to one automatic

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[14] Delays in Vaccine Act cases are granted on request of either party when good cause for the delay is shown. In contrast to a delay, which may involve additional time to file evidence, conduct negotiations or mediation, or comply with various court-imposed deadlines, a suspension of proceedings does not involve an extension of a pending deadline. Rather, it represents the "pause button" in a pending case. In essence, petitioners have requested that I place their case in the same limbo in which the OAP cases rested for many years, pending completion of discovery and litigation of the test cases. The difference here is that petitioners' case is not part of an omnibus proceeding where a test case can be expected to resolve legal or factual issues that may ultimately resolve the case. In the Type 1 Diabetes Omnibus Proceeding, I denied a request for a delay to "let the science develop," as there was no evidence that any pending research projects were focused on vaccine causation. *See Hennessey v. Sec'y, HHS,* No. 01-190V, 2009 WL 1709053 at *9, n.21 (Fed. Cl. Spec. Mstr. May 29, 2009), *mot. for review denied* 91 Fed.Cl. 126 (2010) (significant aggravation claims). While there is no provision in the Vaccine Act for a "scientific stay," petitioners' latest request does not even have pending research as a basis, as there is no evidence that ongoing research will resolve an outstanding question related to vaccine causation.

[15] Petitioners never referred to the article by name, identifying it only by the journal (PEDIATRICS) in which it appeared and the year of publication (2004).

suspension for 30 days if requested, and then a maximum suspension of 150 additional days. Resp. Reply Oct. 16 at 4-5. Respondent observed that I had already granted the maximum amount of time allowed by the Vaccine Rules of the United States Court of Federal Claims. *Id*.

In my 278-page OAP test case decision, *Snyder v. Sec'y, HHS,* No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), about five pages were devoted to a summary and analysis of various epidemiological studies of a relationship between the MMR vaccine and autism. *Id.* at *142-46. The journal article in question, filed as *Cedillo* Respondent's Exhibit P, Tab 38, is referenced in one paragraph of n.397 of my decision, and was otherwise cited at n.228 for the fact that the MMR vaccination was usually administered in the U.S. at 12-15 months of age. This small portion of the decision in *Snyder* summarized many epidemiological studies conducted in the United States, Great Britain, the Netherlands, and Japan, and noted that none of them found any connection between the MMR vaccine and autism. Even accepting petitioners' claims at face value, the other epidemiological studies provided ample evidence of no epidemiological association between MMR vaccination and autism. And, contrary to petitioners' assertions, epidemiological evidence played only a limited role in the rationale for my decision finding insufficient evidence of vaccine causation in *Snyder*.[16]

This is petitioners' fifth formal request to suspend proceedings.[17] In the order filed on March 28, 2014, I previously responded to petitioners' concerns regarding a Congressional investigation as it pertains to a motion to suspend proceedings. To reiterate, petitioners have not provided any evidence that a Congressional investigation is pending on any matter relating to their case.[18] Accordingly, I must apply the Vaccine Act as it is currently enacted and the Vaccine Rules as they currently exist.

Vaccine Rule 9, which addresses requests for a suspension of proceedings, tracks the statutory language in § 12(d)(3)(C) of the Vaccine Act. Under Rule 9(b)(1), a special master must grant an initial motion for suspension for 30 days. Accordingly, I granted petitioners' initial request for a suspension of proceedings. Order, issued May 25, 2012. A special master has the discretion to grant additional motions for

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[16] *See Greenberg v. Sec'y, HHS,* No. 08-024V, 2014 WL 7496604 at *9, n.10 (Fed. Cl. Spec. Mstr. Dec. 08, 2014) (discussing an assertion of fraud regarding OAP epidemiological evidence and noting the limited role that epidemiological evidence played in the test case decisions).

[17] As discussed *infra*, petitioners' first two requests were granted.

[18] In their motion to suspend proceedings, petitioners refer to a forthcoming investigation by the House of Representatives' Committee on Science, Space, and Technology. Pet. Mot. Sept. 30 at 2. There are currently no hearings scheduled on the National Vaccine Compensation Program or on an alleged connection between vaccines and autism spectrum disorder. Committee on Science, Space, and Technology, *Hearings & Legislation*, United States House of Representatives (Feb. 26, 2015, 3:39 PM), http://science.house.gov/legislation?type=hearing.

suspension up to 150 days, but may not grant additional suspensions. Vaccine Rule 9(b)(2). I granted petitioners' motion to suspend proceedings for 150 days in my July 11, 2012 Order. Thus, I cannot grant any further suspensions of proceedings under the Vaccine Rules or the Vaccine Act.

Even were I to interpret petitioners' request as one for a delay rather than a suspension of proceedings, they have not identified a date certain when they will be ready, willing, and able to file the missing evidence. An indefinite stay, delay, or suspension is not warranted; in effect, their case has been delayed since their last substantive filing of medical records on August 16, 2013. No further delays will be granted.

For these reasons, petitioners' motion for a suspension of proceedings is DENIED.

III. Failure to Prosecute.

Petitioners have repeatedly failed to comply with court orders to file the medical records required by § 11(c)(2)of the Vaccine Act and Vaccine Rule 2. These records are essential to establish I.R.I.'s diagnosis and current condition, thus forming the basis for any opinion on causation. As their claim is based on the presence of a mitochondrial disorder, petitioners have the burden to demonstrate that their son has such a disorder. *See Broekelschen v. Sec'y, HHS,* 618 F.3d 1339, 1346 (Fed. Cir. 2010). Moreover, they have asserted that treating physicians agree with them that vaccines are responsible for I.R.I.'s condition, but they have refused to file any records containing such opinions. In effect, they ask me to rule in their favor because they believe vaccines are responsible.

As I have reminded petitioners on several occasions, they cannot simply file a claim, demand compensation, and expect to receive it. The Vaccine Act prohibits a special master from finding entitlement to compensation based on a petitioner's unsubstantiated claims. § 13(a)(1). Petitioners must show preponderant evidence of vaccine causation to obtain compensation. § 13(a). The orders to file medical records and other evidence of vaccine causation have been issued to obtain the evidence necessary for a full and fair adjudication of their claim on behalf of I.R.I. Without the missing records, "they cannot establish the factual underpinning necessary to [their] causation theory." *See, e.g.,* Order, issued Mar. 28, 2014. I have emphasized that their refusal to comply with such orders will result in the dismissal of their claim. *See, e.g.,* Orders filed Feb. 7, 2013, Feb. 28, 2013, and May 13, 2013. During the final conference call, respondent also explained why the evidence of record is insufficient, factually and legally, to meet petitioners' burden to produce preponderant evidence of vaccine causation. Transcript ["Tr."] at 37-49.

Petitioners have had ample opportunity in the last three years to cure the defects in their case. It is not so much that they have failed to do so; it is that they have refused to do so.

Under Vaccine Rule 21(b), a claim may be dismissed "for failure of the petitioner to prosecute or comply with [the Vaccine Rules] or any order of the special master or the court." Vaccine Rule 21(b)(1). *See also Tsekouras v. Sec'y, HHS*, 26 Cl. Ct. 439 (1992), *aff'd per curiam*, 991 F.2d 810 (Fed. Cir. 1993); *Sapharas v. Sec'y, HHS*, 35 Fed. Cl. 503 (1996). For more than 18 months, petitioners have repeatedly refused to comply with orders to file the matters required by the Vaccine Act and Vaccine Rule 2. **Therefore, their claim is DISMISSED for failure to prosecute.**

IV. Evidentiary Record.

The evidence discussed below is based primarily on the filed medical records. I have, however, considered the assertions of petitioners in their petition, status reports, motions, and other filings, but I have placed more weight on the contemporaneously-recorded medical symptoms than those recounted in later medical histories or in petitioners' various filings or arguments. "It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight." *Murphy v. Sec'y, HHS*, 23 Cl. Ct. 726, 733 (1991) (citation omitted); *see also Cucuras v. Sec'y, HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (medical records are generally trustworthy evidence). Memories are generally better the closer in time to the occurrence reported and when the motivation for accurate explication of symptoms is more immediate. *Reusser v. Sec'y, HHS*, 28 Fed. Cl. 516, 523 (1993). "[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later." *Id*. The following medical history and the conclusions drawn therefrom are presented with these legal principles in mind.

The medical records are not complete[19] and petitioners have not filed affidavits. Nevertheless, the contemporaneous medical records from the period surrounding the time in which the allegedly causal vaccinations were administered present a reasonably comprehensive record of I.R.I.'s development, the onset of symptoms of an ASD, the subsequent testing, and some of the treatment I.R.I. received.

[19] Additionally, I note that some of the records appear to have been culled; pages have been left out of lab results and doctors' notes. *See, e.g.,* Pet. Ex. 6, p. 278-82; Pet. Ex. 7, p. 300-01; Pet. Ex. 18, p. 389. Whether this is the result of poor record keeping by I.R.I.'s physicians, disorganization on the part of petitioners, or an attempt to alter evidence is impossible to determine.

A. Early Medical Treatment.

1. Medical and Vaccination History.

I.R.I. was born at 41 weeks gestation after an uncomplicated pregnancy via a vacuum assisted vaginal delivery in November 2006. Pet. Exs. 1, p. 2; 6, p. 250. The vacuum assistance was necessary due to fetal heart rate decelerations. Pet. Ex. 6, p. 250. His Apgar scores were 9 and 9, reflective of a healthy newborn.[20] Pet. Ex. 25, pp. 1, 4.[21] He was discharged to home two days after birth. Pet. Ex. 6, p. 250.

I.R.I. was born into a family with a history of mild developmental delays. His father was delayed in language acquisition, although he developed language without receiving any treatment. Pet. Ex. 10, p. 341. I.R.I.'s maternal cousin was diagnosed with Pervasive Developmental Disorder, Not Otherwise Specified ["PDD-NOS"], a disorder on the autism spectrum. Pet. Ex. 6, p. 251.

His primary medical care was provided by pediatricians at the John Muir Medical Group ["John Muir"], where he usually saw Drs. Andrew Nash, Gregory Hahn, or Lynne Whyte. He had well baby visits a few days after birth and at regular intervals thereafter. At all of these visits through one year of age, he appeared to be developing normally, and his parents expressed no concern about any developmental problems.[22] I.R.I.'s doctors did not seem concerned about his growth and development, and he appeared to be meeting all of his developmental milestones. *See* Pet. Ex. 1, p. 17-25.

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[20] The Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle tone, reflex irritability, and color, with from zero to two points awarded in each of the five categories. *See* DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32d ed. 2012) ["DORLAND'S"] at 1682; NELSON TEXTBOOK OF PEDIATRICS (19th ed. 2011) ["NELSON'S"] at 536-37. In one medical history, Mr. Padmanabhan mentioned an Apgar score of 5, which would be concerning regarding I.R.I.'s condition after birth. Pet. Ex. 7, p. 305. At the initial visit with Dr. Michael Goldberg, Mr. Padmanabhan also provided a medical history which reported an initial Apgar score of 5. *See* Pet. Ex. 5, p. 186. However, these reports were not accurate, as the birth records, when finally filed in August 2013, reflect near-perfect Apgar scores. This miscommunication illustrates the basis for my concern about relying on petitioners' second-hand assertions about I.R.I.'s diagnosis and his physicians' opinions on causation.

[21] Exhibits 24 and 25 are in the same PDF file, with no clear demarcation between the two exhibits. Given that the page numbers restart with "1," this is likely the first page of Pet. Ex. 25.

[22] At the first well child visit a few days after his birth, I.R.I. had lost some weight, but there were no concerns about weight gain thereafter. Pet. Ex. 1, p. 18. A weight check on December 14, 2006 showed that he had regained the weight lost, and was two ounces heavier than he was at birth. *Id.*, p. 19. His weight curve (*id.*, p. 3) reflects that I.R.I.'s weight largely remained between the 25th and 50th percentiles through 18 months of age.

During his first two years, I.R.I. received the recommended childhood vaccines at well child visits.[23] No reactions to any of the vaccinations were reported in the medical records.

There were several sick child visits as well. I.R.I. was seen on January 10, 2007 (about six weeks after birth and the administration of his initial hepatitis B vaccination) and on August 18, 2007 (three months after his most recent vaccination) for minor childhood illnesses. Pet. Ex. 1, pp. 20, 24.

At his well child visit on May 24, 2007, shortly before six months of age, I.R.I. exhibited normal development for his age. He cooed, smiled, reached for a toy, babbled, rolled, and sat with support. Pet. Ex. 1, p. 23. At his nine month well child visit on August 24, 2007, I.R.I.'s parents did not express any concerns about his development. Pet. Ex. 1, p. 25.

At his one year well child visit in December 2007, I.R.I. was walking and saying "mama" and "dada," although not specifically in reference to his parents. They expressed no concerns about his development, and his pediatrician assessed him as "doing great." Pet. Ex. 1, p. 26. He received an influenza vaccination, his initial hepatitis A vaccination, and his fourth Prevnar vaccination at this visit. *Id*., p. 13. According to a history provided to Dr. Haas in October 2010, petitioners had no concerns about I.R.I.'s health or development during his first year of life. Pet. Ex. 7, p. 305.

Later in December 2007, I.R.I. developed a cough and cold with a fever. Pet. Ex. 1, p. 27. His pediatrician diagnosed croup. *Id.* On January 10, 2008, I.R.I.'s parents returned to the pediatrician, reporting that their son had experienced a fever that had since resolved. I.R.I. had a runny nose and cough, and was diagnosed with right otitis media. His parents were told to follow up in 10 to 14 days. Pet. Ex. 1, p. 28. I.R.I.'s symptoms presumably resolved on their own, as petitioners did not return to the pediatrician for several months.

The allegedly causal vaccinations were administered on March 13, 2008, when I.R.I. was 15 months old. At that point, I.R.I. was walking well, had three words (other than "mama" and "dada"), and was imitating housework. Pet. Ex. 1, p. 29. At this visit, he received his fourth DTaP, third Hib, and initial MMR and varicella vaccinations. *Id*.,

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[23] He received his initial hepatitis B vaccination shortly after birth. Pet. Ex. 1, p. 13. At two, four, and six months of age, he received Pediarix, a trade name for combined DTaP, IPV, and hepatitis B vaccines. He also received Hib vaccinations at two and four months of age and Prevnar, the trade name for a pneumococcal vaccine, at two, four, and six months of age. Although not reflected on the preprinted vaccination record, I.R.I. received Rotateq (a trade name for rotavirus vaccine) vaccinations at two, four, and six months of age. *Id.*, pp. 21-23. Additional vaccinations, including those that are alleged to have caused I.R.I.'s condition, are discussed, *infra*.

p. 13. There are no medical records reflecting any reaction to these vaccinations.[24] When asked about these specific vaccinations at their September 2010 initial appointment with Dr. Goldberg, petitioners indicated that I.R.I. had not experienced any reactions. Pet. Ex. 5, p. 185. This contrasts with the assertions in their March 2011 petition.[25]

On April 7, 2008, more than three weeks after the 15 month immunizations, I.R.I. had a cold, cough, rash on his face, a slight fever, and vomiting. He was diagnosed with a viral syndrome. Pet. Ex. 1, p. 30. On April 30, 2008, I.R.I. and his parents returned to the pediatrician. I.R.I. had run a fever the previous day, and was experiencing a decreased appetite and seemed fussy. He also had a rash on his upper trunk, back, and cheeks. I.R.I.'s doctor described him as alert and in no apparent distress. The doctor concluded that I.R.I. had a viral illness with associated exanthema and possible mild gastroenteritis. *Id*., p. 31.

He was next seen at his 18 month well child visit on June 13, 2008. He was reported as bilingual and speaking more than ten words (a gain of language since the 15 month visit) and using eating utensils. He was assessed as a well child and was, according to the pediatrician, "doing great." Pet. Ex. 1, p. 32. No vaccinations were administered at this visit. *Id.*, p. 13.

I.R.I.'s sister was born when he was approximately 18 months old. In a history provided in late April 2009, petitioners recounted some regression in I.R.I.'s development at around the time of his sister's birth. Pet. Ex. 10, p. 339; *see also* Pet. Ex. 7, p. 305.

On July 31, 2008, I.R.I. again experienced fever and vomiting. His tonsils were enlarged without exudate and Dr. Nash believed he had viral pharyngitis with mild gastroenteritis. Pet. Ex. 1, p. 33.

At his two year well child visit on December 2, 2008, I.R.I. was using two-word phrases and had a vocabulary of 40-50 words. However, a concern about "licking" was noted. His pediatrician assessed him as a well child, but this assessment was followed by a note reflecting "slower" social communication development. Although the remainder of the note is difficult to read, it appears to indicate that this would be

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[24] Petitioners contend that they telephonically reported a fever with hardness, redness, and swelling at the site of the vaccinations to I.R.I.'s health care providers at John Muir. Petition at 1. They claim that no record of such a phone call exists because I.R.I.'s pediatric practice does not keep records from phone calls involving minor problems. Tr. at 30-31. As evidence, they filed a letter they wrote to the pediatric practice memorializing a conversation with someone on the practice's staff to that effect. *See* Pet. Ex. 14.

[25] The petition itself is the first indication in any of the filings in this case that petitioners blamed these particular vaccinations for causing or significantly aggravating I.R.I.'s condition, although at his three year well-child visit, Dr. Whyte noted a "long discussion about vaccines." Pet. Ex. 1, p. 46.

followed up at another appointment, and that petitioners should involve I.R.I. in a play group or gymnastics. He received hepatitis A and Flumist (influenza) vaccinations at this visit. Pet. Ex. 1, pp.13, 34-35 (duplicate pages). This consultation note appears to reflect the first report of concerns about I.R.I.'s speech development and behavior.

I.R.I. had diaper rash shortly after the two year well child visit. Pet. Ex. 1, p. 36. Over the period between his second and third birthdays, I.R.I. was also seen for bronchitis in January 2009, a viral illness with cough and congestion in June 2009, and influenza in August 2009.

Although petitioners correctly asserted that I.R.I. had more illnesses after his 15 month vaccinations than before them[26] (Petition, ¶ 16; Tr. at 32), the conclusion that they drew from this—that I.R.I. had immune dysfunction triggered by the 15 month vaccinations—is not supported. None of I.R.I.'s physicians who treated him for these illnesses noted that the number or nature of them suggested any immune dysfunction, and none attributed any of I.R.I.'s ailments to a vaccine. I note that another conclusion could as easily be drawn from the same facts—that I.R.I. had fewer illnesses than the average child experiences from birth to 15 months of age, and a normal number of such illnesses in the 15 months afterwards.[27] Alternatively or additionally, as an older child involved in a play group and playground activities, he simply may have been exposed to more illnesses after 15 months of age.

2. Recognition, Diagnosis, and Treatment of an Autism Spectrum Disorder.

At a pediatric visit on January 20, 2009, when I.R.I. was a little over two years old, his parents expressed concern about his development to Dr. Nash. Pet. Ex. 1, p. 37. Petitioners were concerned primarily with his lack of social development. Although he was in a play group, he was not engaging with other children; rather, he preferred to stand back and observe. They thought I.R.I. had a lot of words and was trilingual, but he did not put two or three words together very often. Petitioners also stated that their

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[26] I.R.I. had four documented sick child visits before the administration of the allegedly causal vaccinations. *See* Pet. Ex. 1, pp. 20 (conjunctivitis in January 2007), 24 (fever in August 2007), 27 (croup in December 2007), 28 (otitis media in January 2008). He had six documented sick child visits in the 15 months following the administration of the vaccinations. *See id.*, pp. 30-31 (viral syndrome in April 2008, followed by a repeat visit three weeks later for a probable viral illness), 33 (viral pharyngitis in July 2008), 36 (diaper rash in December 2008), 38 (bronchitis in January 2009), 40 (viral illness with fever, cough, and congestion in June 2009). It is unclear how petitioners arrived at their repeated assertions that I.R.I. had eight times the number of viral and fungal infections and twenty times the sick days after the March 2008 vaccines than compared to a similar period of time before the vaccinations. *See* Tr. at 32.

[27] Petitioners may have used a longer period for their comparison of I.R.I.'s illnesses before and after the allegedly causal vaccinations, although the petition reflects they used 15 months in both calculations. Petition, ¶ 15. The number of sick days is impossible to calculate from the medical records. What is significant here is that no physician, and certainly not the pediatricians who were treating him, recorded that he had an unusual number of illnesses or that the illnesses were unusually severe.

son had begun licking objects, both at home and at the playground. I.R.I.'s treating physician, Dr. Nash, assessed social delays and possible language delays and referred him to the Regional Center of the East Bay ["RCEB"] for a developmental evaluation. He indicated that I.R.I. would likely need occupational and speech therapy.

On February 2, 2009, I.R.I. was evaluated for speech and language services offered through the RCEB. Pet. Ex. 9, p. 335. During the evaluation, he responded to his name on only one occasion. He made only fleeting eye contact. I.R.I. exhibited maladaptive behaviors, including sensitivity to touch and stimuli and licking non-food objects such as balls and books. *Id.* I.R.I.'s receptive language age equivalent was seven months, while his expressive language age equivalent was 12 months. Pet. Ex. 9, p. 336. According to the evaluation, these delays were not attributable to the multiple languages spoken in the home. *Id.*

In late April and early May 2009, Dr. Rene Wachtel, a developmental pediatrician, and Dr. (Ph.D.) Lori Wensly, a clinical psychologist, conducted a comprehensive evaluation of I.R.I. which included direct observation of I.R.I., a detailed parental history, and the administration of tests measuring cognitive development, communication, adaptive behavior, and behaviors relevant to a diagnosis of autism. Pet. Ex. 10, pp. 343-44. His intellectual performance was within normal limits for his age. *Id.*, pp. 344-45. His fine motor skills were likewise in the normal range, although his gross motor skills were slightly delayed. *Id.*, p. 345. However, he had significant delays in both receptive and expressive language, results that were also reflected on the adaptive skills testing. I.R.I. had "significant impairment" in socialization skills; he interacted and played at the level of a seven month old child. *Id.*, pp. 345-46.

Administration of the Childhood Autism Rating Scale ["CARS"],[28] a diagnostic instrument for autism, resulted in a CARS score of 34, placing him in the mildly autistic range. The diagnosis was "Autistic Disorder." Pet. Ex. 10, p. 348. The evaluation team recommended an "intensive autism treatment program" and genetic testing. *Id.*, pp. 348-49.

Shortly after his diagnosis in the spring of 2009, his parents began pursuing less conventional therapies for treatment. On June 16, 2009, Mr. Padmanabhan and Ms. Srinivas returned to John Muir for a consultation regarding medication and speech delay. They indicated that I.R.I. had been evaluated by the RCEB and diagnosed with speech delay and social anxiety, but "not autism."[29] Pet. Ex. 1, p. 39. He was receiving

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[28] As reflected in the report, CARS is "designed to evaluate the presence and degree of autism in children. It distinguishes children with autism from developmentally handicapped children who are not autistic." Pet. Ex. 10, p. 346.

[29] This entry is correct in that the RCEB did not make an autism diagnosis. Petitioners indicated that I.R.I. had been evaluated by Dr. Wachtel, but either they did not inform the pediatrician of the autism diagnosis or had not yet been informed of it themselves, as an autism diagnosis does not appear on this record. Pet. Ex. 1, p. 39.

one hour of speech therapy a week as well as occupational therapy at home and at the center.

Nevertheless, it appears that petitioners at least suspected an autism diagnosis, as the record for this visit also indicates that they planned to visit a DAN![30] doctor and wanted to follow a biomedical model for I.R.I.'s treatment. *Id*. They wanted the pediatrician to order laboratory testing, as the DAN! doctor they had selected, Thauna Abrin, was a naturopath[31] rather than a medical doctor and thus could not order the tests herself.

Blood testing was performed on June 19, 2009. Only two of the three pages were filed, but most of the results reported were within the reference ranges. A handwritten note at the bottom of the second page reflects "? fighting virus. will repeat LFTs in 2-4 weeks. Sooner prn [as necessary]." Pet. Ex. 1, pp. 88-89. The signature following these notes appears to be the same as that of the physician who met with petitioners on June 16.

Beginning in July 2009, I.R.I. was subjected to a battery of laboratory tests for gastrointestinal pathogens, food allergies, celiac disease, immunoglobulins, vitamin D, blood toxic metals, urinary porphyrins and toxic metals, various viral antibodies, stool parasites, thyroid function, and antinuclear antibodies. *See, e.g.*, Pet. Exs. 1, pp. 61, 63, 64-65, 75-78, 110-14; 2, pp. 127-31, 141; 3, pp. 147-51; 4, pp. 157-83; 5, pp. 208-16. With very few exceptions (mostly involving Dr. Goldberg, whose treatment is discussed, *infra*), the results were within reference ranges or not interpreted as significant by any physician.[32]

At his two and a half year well child appointment on July 8, 2009, I.R.I. was reported to be receiving occupational and speech therapy. Pet. Ex. 1, p. 41. The pediatrician also noted Dr. Wachtel's diagnosis of mild to moderate autism and recorded that I.R.I. was receiving 25-40 hours of ABA therapy per week.[33] Although the

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[30] Defeat Autism Now! ["DAN!"] physicians subscribe to "biomedical" treatment protocols developed by the Autism Research Institute. These treatments may include chelation and other therapies not vetted as efficacious by controlled clinical studies. *Dwyer*, 2010 WL 892250 at *20, *178.

[31] "Thauna Abrin, N.D." was identified in a later record. Pet. Ex. 1, p. 44. The initials "N.D." denote a Doctor of Naturopathy. DORLAND'S at 1233. A naturopathic doctor is one who subscribes to "a drugless system of health care, making use of a wide variety of therapies, including hydrotherapy, heat, massage, and herbal medicine." *Id.* Records identified as those of Dr. Abrin were filed as Pet. Ex. 2, but the records consist solely of laboratory reports. No consultation notes were filed.

[32] The results from many of these tests were summarized by Dr. Fadi Haddad, a pediatric gastroenterologist who saw I.R.I. in September 2009. He did not discuss their significance, except as noted *infra*. *See* Pet. Ex. 1, pp. 124-25 (summarizing and discussing test results).

[33] "ABA" stands for "applied behavioral analysis," and is one of the few autism therapies demonstrated to be effective in improving autism symptoms. *Dwyer,* 2010 WL 892250 at *272, n.650.

pediatrician recorded that I.R.I. was "[at] milestones now," the word "milestones" likely refers to a therapy practice, not developmental milestones.[34] The pediatrician ordered the laboratory tests requested by Dr. Abrin, but had questions about the use of supplements and which tests to delay if they were unable to get all of them performed. Genetic tests were also ordered to complete the work up for newly diagnosed autism, but unlike the myriad of tests ordered for Dr. Abrin, if these tests were performed, the results were not filed. *Id*.

On August 10, 2009, Mr. Padmanabhan visited his son's pediatrician to go over the laboratory test results, although it is unclear how I.R.I.'s doctor interpreted the results (or even which tests were discussed).[35] The pediatrician recommended cutting I.R.I.'s vitamin dosage in half. *Id.* At the time of this appointment, I.R.I. was taking vitamins, omega 3, probiotics, and grape seed extract, and considering methyl B12 injections, none of which had been prescribed by the pediatric practice. *Id*.

At a John Muir pediatrics visit in early September 2009, petitioners reported that I.R.I. was beginning a gluten- and casein-free diet on a diet plan developed by Dr. Abrin.[36] Pet. Ex. 1, p. 45. Doctor Abrin wanted I.R.I's pediatrician to write a prescription for a medication made by a compounding pharmacy. Petitioners indicated that with I.R.I.'s third birthday approaching, the responsibility for his therapy would switch from RCEB to the school system. The pediatrician agreed to write prescriptions with a diagnosis so that petitioners could submit a request to their insurance for reimbursement of costs associated with I.R.I.'s treatment. *Id.*

On September 23, 2009, I.R.I. visited Dr. Haddad, a pediatric gastroenterologist, the result of a referral from one of I.R.I.'s pediatricians. Pet. Ex. 1, pp. 124-26. Doctor Haddad identified tests results he found significant as "a positive gliadin IgG, several food allergen positivities on the ELISA IgG, elevated vitamin B12 level, low ferritin, history of elevated transaminases [AST and ALT] in June 2009 with improvement of ALT (now normal), but mild elevation of the AST." *Id*., p. 125. He provided five differential diagnoses: celiac disease (although he noted that the gliadin IgA was normal, making this disease less likely); allergic enteropathy (commenting that the

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[34] Although I.R.I. was listed as doing well on fine and gross motor skills, his speech and socialization skills were not normal, making it unlikely that a physician would assess him as meeting all his developmental milestones. Pet. Ex. 1, p. 41. Later records note that he was receiving some therapy "@ Milestones" (*id.,* p. 44) and that "Milestones working great for him for ABA—good relationship [with] therapist." (*id*., p. 45). Thus, it appears that the reference to "milestones" at the July 8, 2009 visit was referring to a place, rather than a developmental achievement.

[35] At least some of the results from Dr. Abrin's testing were filed in both Pet. Exs. 1 (the John Muir pediatrics practice) and 2 (Dr. Abrin's records)).

[36] Many children with ASD are placed on this diet, although there is little evidence of its efficacy in any controlled studies. *See Snyder*, 2009 WL 332044, at *163.

ELISA IgG tests were "difficult to interpret clinically"); inflammatory bowel disease (also less likely); lactose intolerance; and small bowel bacterial overgrowth. He recommended further testing. *Id*. Although Dr. Haddad wanted to see I.R.I. again in a month, no further records from his office were filed.

However, the results from the tests Dr. Haddad ordered were filed. Serological testing for anti-gliadin antibodies was negative; genetic testing for susceptibility to celiac disease showed I.R.I. was at low risk; AST and ALT were within reference ranges; his vitamin B12 level remained high;[37] and allergen testing for chicken, corn, eggs, milk, soybean, and wheat were all within reference ranges. Pet. Ex. 3.

At I.R.I.'s three year well child visit,[38] he was seen by Dr. Whyte. Pet. Ex. 1, pp. 46-49 (the pages are filed out of order, with p. 48 being the initial page of this record). She noted that I.R.I. was on a diet free of gluten, casein, and soy, taking multiple supplements and vitamins, and receiving methyl B12 shots at home. She also noted that since November, I.R.I. had been seeing a Dr. Jepson at "Totville House (?sp) in Texas."[39] Petitioners informed her that Dr. Jepson focused on treating GI symptoms initially via antibiotics and antifungal medications before addressing the immune system, followed by "metals/toxins." Petitioners reported that I.R.I. was in school six hours per day and was receiving nine hours of private speech, sensory, and occupational therapy each week. *Id.* Doctor Whyte's physical examination of I.R.I. found good strength and tone. *Id*., p. 46. Neurologically, he was alert and oriented. Her diagnoses were autism and speech delay, with a notation that he was making good progress with therapy. *Id*.

Doctor Whyte also noted a "long discussion about vaccines" with his parents, but the substance of the discussion is not set forth in the records. She provided names of immunologists and metabolic doctors in the area to petitioners in case "they want to see

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[37] The fact that I.R.I. was receiving methyl B12 (vitamin B12) therapy may account for the high level found. Pet. Ex. 1, p. 48; *see also* laboratory report from December 6, 2010 (showing a B12 level of 1500, with a reference range of 180-914); Pet. Ex. 5, p. 221 (records from Dr. Goldberg, who also prescribed methyl B12 therapy).

[38] The date of this visit is unclear. Although the record contains an "Encounter Date" entry of 10/15/2009 in the upper right corner of Pet. Ex. 1, p. 48, there are also dates of "1/28/2010" reflected. Substantive entries in the record (*i.e.*, use of past tense ("treatment plan began 11/09") in reference to Dr. Jepson's treatment of I.R.I), I.R.I.'s birthdate in late November, the references to treatment received through the school system, and the date of the prior year's well child visit in January 2009, all suggest that the January 28, 2010 date is correct.

[39] At that time, Dr. Bryan Jepson, an emergency medicine physician, worked at "Thoughtful House" in Austin. *See* http://www.integrativesportsandwellness.com/dr.-bryan-l.-jepson-md.html. Records from Dr. Jepson are filed as Pet. Ex. 4. However, those records consist only of a series of laboratory results, the earliest of which were dated as having been performed in February 2010. *See* Pet. Ex. 4, p.153. A "comprehensive food panel" test performed in June 2010 was also filed. Pet. Ex. 1, pp.106-07.

someone based on information they get from their DAN[!] Doctor" or "to discuss metabolic/mitochondrial concerns further." *Id*., p. 46.

In summary, by the time I.R.I was a little over three years of age, he had a diagnosis of an autism spectrum disorder, for which he was receiving ABA, speech, and occupational therapy. While some of I.R.I.'s health care providers speculated that he might have some other developmental disorder, ASD remains I.R.I.'s only developmental diagnosis.

B. Later Diagnoses and Treatment.

By the fall of 2010, petitioners began seeking explanations other than autism for I.R.I.'s condition. Petitioners explored immune system dysfunction and possible metabolic or mitochondrial disorders with several practitioners in 2010-11.

1. Immune System Problems.

One explanation advanced by a treating physician, Dr. Goldberg, was that I.R.I. has an immune system dysfunction.[40] Immune dysfunction plays a prominent role in petitioners' causation theory. *See* Tr. at 13.

On September 2, 2010, at I.R.I.'s initial consultation with Dr. Goldberg, petitioners told him their son developed normally until he was 18 months old and that he had no reactions to his MMR vaccine received March 13, 2008. Pet. Ex. 5, p. 185. This is in marked contrast to the assertions in the petition for compensation filed approximately six months later. Doctor Goldberg felt I.R.I. had a neurocognitive dysfunction and was on the "Autistic Spectrum/NIDS."[41] Pet. Ex. 5, p. 189. He advised stopping supplements; continuing Nizoral;[42] switching from the antiviral drug Valtrex[43] to

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[40] Although petitioners reported to Dr. Whyte that Dr. Jepson was treating I.R.I. with antibiotics and antifungal drugs, suggesting that he was treating autism symptoms as an immune system problem, no office notes from Dr. Jepson were filed. Thus, there is no physician interpretation of the many laboratory reports that appear in Pet. Ex. 4. None of the notes on the test results indicate a concern about immune system dysfunction.

[41] "NIDS" stands for "Neuro-Immune Dysfunction Syndrome." *See Dwyer,* 2010 WL 892250, at * 276 n. 660. The mission statement for the NIDS organization asserts that autism, obsessive compulsive disorder ["OCD"] and "related conditions are not developmental disorders but are the result of a disease process that is treatable." NIDS is described as "a complex immune/complex viral disorder." *See* http://www.nids.net. This website features a book by Dr. Goldberg titled "The Myth of Autism: How a Misunderstood Epidemic is Destroying Our Children."

[42] Nizoral is an anti-fungal medication. PHYSICIAN'S DESK REFERENCE ["PDR"] at 123 (66th ed. 2012).

[43] Valtrex is used to treat viral infections. PDR at 127.

another antiviral drug, Famvir;[44] and considering the use of an SSRI[45] in the evening. *Id*. He later prescribed Paxil.[46] *Id*., p. 190.

Although Dr. Goldberg made a diagnosis of immune dysfunction on several occasions,[47] laboratory evidence of such dysfunction is lacking. For example, Pet. Ex. 4, p. 156, is a lab report from February 2010, reflecting immunoglobulin subclass testing, with all results within reference ranges. Similarly, tests for various types of immunoglobulins (IgG, IgA, IgM), also performed in February 2010, all show results within reference ranges. *Id*., p. 154. These test results do not support the diagnosis of immune system dysfunction. Antibody testing performed in February 2011 showed no detectable rubella antibodies, but I.R.I. had high levels of IgG antibodies to human herpes virus ["HHV"] 6, indicating current or past infection. Pet. Ex. 5, p. 248. This was a marked change from his previous HHV 6 test, which had detected no antibodies just a few months earlier. *See* Pet. Ex. 5, p. 249. A high level of antibodies is evidence of an immune response to infection. *See Snyder*, 2009 WL 332044, at *87. Other antibody testing ordered by Dr. Goldberg likewise reflected antibody responses to infection.[48]

Doctor Goldberg's records reflect the testing he ordered throughout 2010-11, but do not reflect the significance of any of the results, except for noting that an EEG was normal[49] (Pet. Ex. 5, p. 191) and that I.R.I.'s elevated carnitine level was "consistent with" SCAD deficiency (*id*., p. 199). In general, his records reflect improvement on

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[44] Famvir (famciclovir) is used to treat various types of herpes infections. DORLAND'S at 678.

[45] SSRI stands for "selective serotonin reuptake inhibitor." *See* Neil M. Davis, MEDICAL ABBREVIATIONS (15th ed. 2011), at 308. These drugs are used as antidepressants.

[46] Paxil is used to treat depression, social anxiety, obsessive compulsive disorder ["OCD"], panic disorder, generalized anxiety disorder, and posttraumatic stress disorder. PDR at 1264.

[47] For example, in December 2010, Dr. Goldberg signed a form authorizing administration of an antiviral drug used to treat herpes infections to I.R.I. during school hours. The form reflected a diagnosis of immune dysfunction. Pet. Ex. 5, p. 202.

[48] Viral antibody testing showed prior exposure to Epstein Barr virus ["EBV"], HSV I/II [herpes simplex virus types 1 and 2], cytomegalovirus, and HHV6 [human herpes virus type 6] (Pet. Ex. 5, p. 209), but there was no clinical evidence of active infection at the time of testing. I note that I.R.I. had earlier experienced several illnesses that were diagnosed as likely viral in nature by his pediatrician (*see* Section IV.B.1, *infra*), so the positive antibody test results would be expected. I also note that I.R.I. apparently recovered from each of these prior illnesses, indicating that he was in fact mounting an effective immune response. Doctor Goldberg's records do not reflect any connection between this evidence of past viral infection and I.R.I.'s ASD or possible SCAD deficiency diagnoses.

[49] On January 28, 2011, I.R.I. underwent an awake electroencephalogram ["EEG"]. DORLAND'S at 594. According to Dr. Goldberg, the EEG was "normal without evidence of focality, epileptiform discharges or seizures." Pet. Ex. 5, p. 191. This finding, however, did not preclude a diagnosis of seizures or epilepsy. Pet. Ex. 8, p. 333.

various antiviral therapies,[50] but I note that I.R.I. was continuing to receive speech, occupational, and ABA therapies, and thus it is difficult to attribute improving speech and behavior to antiviral therapy, rather than speech or ABA therapy.

Other records of immune system testing by the Mayo Clinic in 2011 were filed as Pet. Ex. 18, pp.389-96. The ordering official is simply identified as a "staff physician." *Id*. Although the results were not interpreted by a physician, the only result outside the reference range was an elevated "IgM+% of CD19+B cells." Pet. Ex. 18, p. 390. These mostly normal results "did not necessarily rule out CVID."[51] There is no evidence that I.R.I. was ever diagnosed with CVID.

In July 2011, another physician, Dr. Kendal Stewart,[52] opined that I.R.I.'s test results were consistent with Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal infections ["PANDAS"]. Pet. Ex. 17, p. 388. However, Dr. Stewart stopped short of formally diagnosing I.R.I. with PANDAS. PANDAS is considered a subtype of obsessive-compulsive disorder ["OCD"] and is not associated with autism. Patients with PANDAS experience a "sudden and dramatic onset or exacerbation of OCD or tic symptoms, associated neurologic findings, and a recent streptococcal infection." NELSON'S at 919.

Although Dr. Goldberg diagnosed I.R.I. with an immune system disorder, he never specified the precise type of the disorder. He never specifically opined that I.R.I.'s autism symptoms were caused by a dysfunctional immune system. Moreover, the immune system testing performed by several different physicians involved in I.R.I.'s care did not show objective evidence that I.R.I.'s immune system was dysfunctional. He had adequate immunoglobulin levels overall and had memory cells (as reflected by IgG

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[50] In October 2005, Dr. Goldberg recorded that I.R.I. had improved attention and speech with Famvir, although his speech was still not consistent. Pet. Ex. 5, p. 200. By mid-November, he recorded that I.R.I. had become more aware and his speech had improved. *Id.*, pp. 190-91, 204. His development remained much the same through the next month, though his eye contact was noted to improve on higher doses of Paxil. *Id*., pp. 202-03. In February 2011, Dr. Goldberg noted I.R.I.'s speech had improved, but feedback from the ABA therapist noted slow and inconsistent progress. Pet. Ex. 5, p. 205.

[51] "CVID" is an abbreviation for Common Variable Immune Deficiency. DORLAND'S at 451.

[52] Doctor Stewart's specialty is not reflected in his records or letter (*see* Pet. Exs. 12-13, 17), but his practice is identified as "NeuroSensory Centers of America – Austin." Pet. Ex. 17, p. 388. It appears from the materials in Pet. Ex.12 that Dr. Stewart's practice subscribes to the theory that ASD is caused by "heavy metals," environmental toxins, or "neurotropic viral groups." Pet. Ex. 12, pp. 356-57. Petitioners' Exhibit 12 includes brief synopses of 18 "recent articles of interest." None of the articles were actually filed in this case. Moreover, the mercury and oxidative stress theory, which appears to be encompassed in these articles, was considered and rejected in the OAP Theory 2 test cases. *See Dwyer*, 2010 WL 892250; *King v. Sec'y, HHS,* No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y, HHS,* No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

levels) to several common viruses, indicating that he had previous viral infections and recovered.

2. Evidence Regarding Metabolic and Mitochondrial Disorders.

a. Background Information.

Mitochondria are small organelles (structures inside cells) that turn food and oxygen into the body's supply of chemical energy. In addition to energy production, mitochondria are also responsible for maintaining proper functioning of various organs. When mitochondria do not function as they should, many organ systems likewise fail to work properly. *See Bast v. Sec'y, HHS,* No. 01-565V, 2012 WL 6858040 at *24 (Fed. Cl. Spec. Mstr. Dec. 20, 2012), *mot. for review denied sub nom. [M.S.B.] by Bast v. Sec'y, HHS,* 117 Fed.Cl. 104 (2014); *appeal dismissed sub nom. M.S.B. ex rel. Bast v. Sec'y, HHS,* 579 Fed.Appx. 1001 (2014).

"Mitochondrial disease is not a single entity but, rather, a heterogeneous group of disorders characterized by impaired energy production due to genetically based oxidative phosphorylation dysfunction." Court Exhibit I, R. Haas, et al., *Mitochondrial Disease: A Practical Approach for Primary Care Physicians,* PEDIATRICS, 120(6) 1326-33, (2007) at 1326 [hereinafter "Haas, Court Ex. I"]. Physicians have difficulty definitively diagnosing a mitochondrial disease as patients often present with a wide array of symptoms. *Id.* There is no "definitive biomarker that characterizes mitochondrial disease in all patients." *Id.* at 1331. "Mitochondrial diseases are usually progressive and multisystemic," typically affecting organs with "a high energy demand, including skeletal and cardiac muscle, endocrine organs, kidney, nonmucosal components of the intestinal tract, retina, and the central nervous system." *Id*. at 1327.

A SCAD disorder is a fatty acid oxidation disorder (an inborn error of metabolism (metabolic disorder)) (*see* NELSON'S at 456, 460) that may affect mitochondrial function, but it is not a primary mitochondrial disorder or disease. Haas, Court Exhibit I, at 1330 (discussing secondary mitochondrial dysfunction caused by a defect in fatty acid and other metabolic disorders); N. Wolf and J. Smeitink, *Mitochondrial disorders: A proposal for consensus diagnostic criteria in infants and children,* NEUROLOGY 59: 1402-06 (2002) at 1404-05, filed as Court Ex. II [hereinafter "Wolf and Smeitink, Court Ex. II"] (discussing secondary respiratory chain involvement of fatty acid oxidation disorders).

b. I.R.I.'s Possible Metabolic or Mitochondrial Disorder.

The issue of whether I.R.I. might have a metabolic or mitochondrial disorder was first raised by I.R.I.'s parents at his three year well child visit with Dr. Whyte. Pet. Ex. 1, p. 46. She offered to refer them to a metabolic specialist to discuss their concerns. *Id.*

In February 2010, I.R.I. was evaluated for "in toeing" by Dr. Scott Hoffinger, the Director of Children's Orthopaedic Associates, a part of the Children's Hospital and

Research Center in Oakland. In a letter to I.R.I.'s pediatrician, Dr. Hoffinger noted that I.R.I.'s parents told him that their son had "some type of metabolic disorder" being treated by a doctor in Texas. Pet. Ex. 1, p. 115. He referred them to a rehabilitation doctor, Elaine Pico, who was "generally quite receptive to looking at kids with slightly different diagnoses and trying to put together a treatment plan." *Id*., pp. 115-16.

A possible mitochondrial disorder was mentioned in March 2010, when I.R.I. saw Dr. Pico. Petitioners told her that I.R.I. was "on the spectrum" with "mitochondrial dysfunction." Pet. Ex. 1, p. 117. Petitioners also reported that I.R.I. had been recently diagnosed with "heavy metals"[53] and was undergoing a homeopathic detox for mercury and lead.[54] Petitioners told Dr. Pico that their son had undergone an adenoidectomy to resolve obstructive sleep apnea in early 2009—the only mention of this or any other surgical procedure in the records.[55] *Id*. Petitioners also informed Dr. Pico that I.R.I. had allergies to gluten and casein. After examining I.R.I., Dr. Pico observed that I.R.I. had "features consistent with being on the spectrum." *Id.*, p. 118.

In a history provided to Dr. Goldberg at the initial visit on September 2, 2010, Mr. Padmanabhan indicated that Dr. Abrin did testing that showed mitochondrial dysfunction, but the records do not reflect which test results were involved. Pet. Ex. 5, p. 187. Doctor Goldberg apparently did not find the results significant, as he recommended waiting before conducting any further mitochondrial testing. Pet. Ex. 5, p. 190.

In September and October 2010, I.R.I. saw several new specialists. The first was Dr. Jonathan Bernstein, a geneticist at Lucile Packard Children's Hospital, who first saw I.R.I. in September. The second was a specialist in mitochondrial and metabolic disorders, Dr. Haas, at Rady Children's Hospital, who first saw I.R.I. in October.

I.R.I.'s parents were referred by Dr. Jepson to Dr. Bernstein to discuss "the diagnosis, management and counseling for the findings of autism." Pet. Ex. 6, p. 250. At the initial visit on September 13, 2010, Dr. Bernstein discussed a possible genetic link to autism but informed petitioners that I.R.I.'s "history and physical exam are not strongly suggestive of a specific genetic etiology for his autism at this time." Pet. Ex. 6, p. 252. He noted that only 5% to 20% of autism cases have a single identified genetic cause. *Id*.

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[53] No records reflecting such a diagnosis have been filed.

[54] Nothing regarding this treatment was filed.

[55] General anesthesia may be hazardous in children with mitochondrial disorders and a "rapidly progressive disease course" involving sudden regression may be seen after surgery. Haas, Court Ex. I at 1327 (Table 1); 1330. If I.R.I. had a mitochondrial disorder diagnosis at the time of the surgery, there would likely be records reflecting this diagnosis in the pre-surgical screening.

However, the language history provided by petitioners to Dr. Bernstein was significantly different from the reports in the contemporaneous records. Petitioners reported to Dr. Bernstein that I.R.I. "experienced a setback in his language skills such that he was speaking only a few words at age 2." Pet. Ex. 6, p. 250. I.R.I.'s pediatric records reflect that at one year of age, he was saying "mama" and "dada," albeit not with specificity. Pet. Ex. 1, p. 26. At the 15 month well child visit (when the allegedly causal vaccinations were administered), he had three words, in addition to "mama" and "dada." *Id*., p. 29. He had more than 10 words by the time of his 18 month well child visit. *Id*., p. 32. At his two year well child visit on December 2, 2008, I.R.I. was using two-word phrases and had a vocabulary of 40-50 words. *Id.*, pp. 34-35 (duplicate pages). Either petitioners conflated events in I.R.I.'s language development or deliberately misinformed the geneticist. Petitioners also reported many respiratory illnesses in the second year of I.R.I.'s life, with the contemporaneous medical records reflecting only four upper respiratory illnesses that year.

To pursue a potential genetic cause for I.R.I.'s condition, Dr. Bernstein recommended array-based comparative hybridization and DNA testing for Fragile X Syndrome.[56] Petitioners declined to pursue these tests. Pet. Ex. 6, pp. 252, 255. Petitioners were, however, interested in metabolic screening tests, which were ordered. *Id*., pp. 252-53.

The results from the metabolic testing were abnormal. An undated addendum to Dr. Bernstein's report indicated that the urine organic acid test results from a sample collected on October 7, 2010, showed increased levels of ethylmalonic and methylsuccinic acids. Plasma amino acids were normal. I.R.I.'s plasma lactate was reported as quite high on one test and slightly high on the other. His ammonia level was very slightly elevated. The urine organic acid test was repeated on October 14, with similar results. Additionally, an acylcarnitine profile from October 14 showed an elevation of C4 acylcarnitine, but free carnitine and total carnitine were within reference ranges. Pet. Ex. 6, pp. 253 (addendum), 259-66, 274, 286 (test results). According to Dr. Bernstein and the laboratory report, these results suggested that I.R.I. might have a SCAD deficiency. *Id.,* pp. 253, 264.

While a SCAD deficiency diagnosis was not made at that (or any other) time,[57] Dr. Bernstein explained to petitioners that the disorder "has been associated with developmental differences," but that the "current consensus is that it is not consistently associated with developmental disorders." Pet. Ex. 6, p. 253. *See* Haas, Court Ex. I, at

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[56] I.R.I.'s pediatrician recommended a Fragile X test in July of 2009, but no results appear in the records filed.

[57] In an Order dated January 8, 2014, I erroneously indicated that Dr. Bernstein had diagnosed I.R.I. with a SCAD deficiency and cited to Pet. Ex. 6, pp. 253-54. These pages reflect that tests performed on I.R.I. were "suggestive" of SCAD disorder, but noted that the family had been counseled that a SCAD diagnosis had not been confirmed. Pet. Ex. 6, p. 253.

1328; *see also* Court Exhibit IV, E. Morava, et al., *Mitochondrial Disease Criteria: Diagnostic Applications in Children,* NEUROLOGY, 67(2) 1823-26 (2006) at 1824 [hereinafter, "Morava, Court Ex. IV"]. Doctor Bernstein recommended confirmatory testing for I.R.I. and screening for his younger sister as well. Pet. Ex. 6, p. 253. He placed I.R.I. on levocarnitine. *Id*.

On October 19, 2010, Mr. Padmanabhan took his son for an initial visit with Dr. Haas to discuss I.R.I.'s ASD and a possible metabolic disorder. Pet. Ex. 7, p. 305. He reported no concerns about I.R.I. in his first year of life, and some regression in I.R.I.'s development at about 18 months of age when his sister was born. He also reported a loss of all words, but did not specify when such loss occurred.[58] *Id*. Doctor Haas reviewed the most recent laboratory testing. He noted the high plasma lactate level from October 7, 2010 (*id*., p. 306), but noted that the blood draw was difficult, a common reason for elevated lactate levels (*see also* Haas, Court Ex. I, at 1328-29). He concluded that he did not have enough information to exclude a mitochondrial disorder and suggested an EEG, skin and muscle biopsies, a lumbar puncture, a brain MRI, and blood, urine, and plasma tests. Pet. Ex. 7, p. 306.

According to petitioners, they declined to pursue some of the recommended tests. Pet. Status Report, filed Mar. 7, 2013, at 3. Tests ordered by Dr. Haas and performed on the date of the visit included a plasma acylcarnitine profile, a comprehensive metabolic panel, plasma ammonia, lactic acid, pyruvic acid, and a carbohydrate deficient transferrin test. Pet. Ex. 7, pp. 306, 312-18, 322.[59] The lactic acid test was high, but much lower than the lactic acid test results from October 7, 2010. Pyruvate was also elevated. Pet. Ex. 7, pp. 293-94. I.R.I.'s plasma acylcarnitine profile showed several abnormal results, and the laboratory interpretation stated that the results "[m]ay indicate Medium-chain 3-ketoacyl-CoA thiolass (MCKAT) deficiency" or that the results might "be secondary to generalized mitochondrial dysfunction." *Id*., p. 297. His carbohydrate tests were normal, a finding "not consistent with a congenital disorder of glycosylation." *Id*., p. 295.

His metabolic panel also indicated elevated levels of blood urea nitrogen, total protein, and albumin, with low levels of total bilirubin and ammonia. *Id.*, pp. 298-99. In additional testing performed on samples collected on November 1, 2010, I.R.I.'s excretion of ethylmalonic acid ["EMA"] was markedly elevated, suggesting a possible SCAD deficiency or mitochondrial respiratory chain defect. *Id*., p. 303. The report indicated that a SCAD deficiency presenting in early childhood was usually a "milder form with hypotonia and developmental delay" and that an "EMA aciduria might be the only biochemical feature of ACAD deficiency." *Id*., p. 304. Repeat testing showing elevations of EMA and C4-carnitine was conducted in January 2011, with the laboratory

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[58] The contemporaneous records do not reflect any complete loss of words at any time.

[59] These test results appear at several other places in Pet. Ex. 7.

noting that the combination of the two elevations was "consistent with SCAD deficiency, a disorder of fatty acid oxidation." *Id*., pp. 326-27.

On October 21, 2010, Dr. Goldberg's records reflect that an unidentified "Stanford doctor" believed I.R.I. might have a mitochondrial disorder and wanted him to start taking Levocarnitine. Doctor Goldberg refused to prescribe the medication without proof of some mitochondrial disorder. He offered to re-test I.R.I. but said that it would not change his current treatment plan. Pet. Ex. 5, p. 200.

The Mayo Clinic tested I.R.I. for a SCAD mutation in January 2011. The laboratory identified one known mutation, one known variant, and two variants of unknown significance. Pet. Ex. 6, p. 289.[60] While "these findings increase the likelihood of a diagnosis of SCAD deficiency," the laboratory cautioned that such a diagnosis "should not be based on this analysis alone" and advised a genetic consultation. Pet. Ex. 6, p. 290. Parental DNA studies, follow-up visits, and counseling were to be coordinated through the biochemical genetics clinic at Lucile Packard Children's Hospital. Pet. Ex. 6, pp. 254-58. A second addendum to Dr. Bernstein's initial report, dated February 8, 2011, reflected that I.R.I.'s "biochemical findings are potentially explained" by some of the mutations and substitutions. Pet. Ex. 6, p. 292. The addendum stopped short of diagnosing I.R.I. with SCAD and recommended parental DNA studies to determine if all the DNA changes were on the same chromosome. *Id.*

It does not appear that any additional testing for a mitochondrial disease was performed. The diagnosis of a mitochondrial disease is difficult to make, even with additional testing. The Haas article, Court Ex. I, states that a "definitive diagnosis of mitochondrial disease cannot be based on biochemical findings alone." *Id*. at 1330. In fact, some patients with suspected mitochondrial disease have, upon further testing, been given definitive diagnoses involving copper-metabolism disorders, lysomal disorders, and others. *Id*. at 1331.

c. Other Testing.

On July 27, 2011, I.R.I. underwent another EEG. Dr. Olson, who performed the procedure, determined that the results were abnormal and noted a "mild, diffuse, encephalopathy." Pet. Ex. 20, p. 416. Notably, Dr. Olson did not convey any opinion as to when I.R.I.'s encephalopathy developed. Dr. Olson also found that I.R.I. had an

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[60] The test results themselves are also filed as Pet. Ex. 6, pp. 256-58. The report reflects a sequence change in Exon 10 of the ACADS gene as a "known mutation associated with abnormal SCAD activity." *Id*., p. 256. The gene variants were unlikely to cause disease themselves, but in the presence of the known mutation, they "increase the likelihood of a diagnosis of SCAD deficiency." *Id*., p. 257. The report stopped short, however, of concluding that I.R.I. had a SCAD deficiency.

increased risk of seizures, but that there was "no evidence of an epileptic encephalopathy."

An October 28, 2011 brain pattern test (a qualitative EEG) was not interpreted by any physician. Pet. Ex. 21. It was the most recent medical record filed. Petitioners have not provided any information about any medical care or treatment their son has received for the past three and a half years.

d. Conclusions Regarding Metabolic and Mitochondrial Diagnoses.

There is nothing in the record indicating whether I.R.I. ever received a definitive diagnosis of a SCAD deficiency. Had any reputable physician opined that I.R.I. has a SCAD deficiency, I would have no difficulty in finding preponderant evidence that he does. In the absence of evidence of such a diagnosis, I cannot make this finding.

Evidence that I.R.I. has a primary mitochondrial disorder, the course of which could be significantly aggravated by a physiologic stressor such as illness, infection, or surgery, is utterly lacking. At best, I.R.I. has some test results suggesting a possible mitochondrial dysfunction, but petitioners have opted against the more definitive testing suggested by Dr. Haas.

Even assuming I.R.I. has a fatty acid oxidation disorder, such conditions are "inborn," not acquired. An inborn error of metabolism may induce some secondary mitochondrial dysfunction, but it does not constitute the type of primary mitochondrial disorder that may lead to sudden regression or decompensation. The distinction between dysfunction secondary to primary mitochondrial disorders and dysfunction secondary to metabolic diseases is made very clearly by Dr. Haas in Court Ex. I at 1330.

The record is devoid of proof that a SCAD deficiency can be significantly aggravated by a vaccine. The only evidence regarding SCAD that petitioners filed discusses the misfolding of proteins in SCAD. Pederson, Pet. Ex. 15. The authors identified several variations of the ACADS[61] gene in patients with SCAD deficiency, but noted that the same variations are also found in 14% of the normal population. Mice with the variant SCAD proteins demonstrated increased protein misfolding. The authors proposed that SCAD deficiency was a disorder of protein folding. While this article offers an interesting perspective on SCAD, it does not provide any information relevant to petitioners' claim. The article does not in any way discuss how vaccines impact SCAD patients. Moreover, petitioners have steadfastly refused to file medical documentation demonstrating that their son does indeed have a SCAD deficiency. Thus, the article is not relevant to the adjudication of their claim.

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[61] "ACADS" is an acronym for acyl-CoA dehydrogenase, an enzyme that is responsible for catalyzing certain reactions integral to the production of cellular energy. *See* DORLAND'S, p. 25.

The next step in analyzing petitioners' causation claims examines the possible bases for a finding of entitlement to compensation in light of the evidentiary record.

V. Alternative Base for Dismissal.

Although there are ample grounds to dismiss this case for failure to prosecute, I elect to rule in the alternative. In so doing, I treat petitioners' assertions that the record as it now stands establishes entitlement to compensation as the functional equivalent of either a motion for summary judgment or a request that I rule on the record.

A. Summary Judgment.

Petitioners' repeated assertions that they have established their entitlement to compensation could be construed as a motion for summary judgment. Summary judgment is permitted under the Vaccine Act. *See* § 12((d)(2)(C)) (requiring the Vaccine Rules to "include the opportunity for summary judgment"). A special master may "decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgment, in which event the procedures set forth in [Rule 56 of the Rules for Court of Federal Claims ("RCFC")] will apply." Vaccine Rule 8(d). Summary judgment standards in vaccine cases are the same as those in any other case. *Jay v. Sec'y, HHS,* 998 F.2d 979, 983 (Fed.Cir. 1993).

Under RCFC 56, summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." A material fact is one "that would affect the outcome of the litigation." *Lowrie v. Sec'y, HHS,* No. 03-1585V, 2007 WL 2734999, at *5 (Fed. Cl. Spec. Mstr. Aug. 31, 2007) (citing *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986)). There is a genuine issue if "the evidence would permit a reasonable trier of fact to find in favor of the nonmoving party." *Lowrie,* 2007 WL 2734999 at *5.

Proof that the vaccinee suffers from the injury claimed is a matter that has a substantial impact on the outcome of a vaccine case. *See Broekelschen,* 618 F.3d at 1346; *Lombardi v. Sec'y, HHS,* 656 F.3d 1343, 1352 (Fed. Cir. 2011) ("under *Broekelschen,* identification of a petitioner's injury is a prerequisite to an *Althen* analysis of causation."). Thus, a diagnosis of a metabolic or mitochondrial disorder, or lack thereof, may be considered a "material fact."

No findings of fact can be made in deciding a motion for summary judgment; if fact finding is necessary, logically there must be some factual dispute. *See Jay,* 998 F.2d at 983. In summary judgment, the court must draw "all justifiable factual inferences . . . in favor of the non-movant." *Shell Oil Co. v. U.S.,* 751 F.3d 1282, 1290 (Fed. Cir. 2014) (*quoting Ford Motor Co. v. U.S.,* 378 F.3d 1314, 1316 (Fed. Cir. 2004)); *see also Anderson,* 477 U.S. at 255.

Petitioners cannot establish that there are no genuine issues as to material fact. Such threshold issues as whether I.R.I. has any of the diagnoses they claim for him remain in dispute. Diagnoses aside, their theory of how vaccines may have caused the symptoms listed in their petition remains unclear.[62] Regardless of the theory, there is no expert's (or even a treating physician's) opinion supporting vaccine causation. Their chain of logic connecting the March 2008 vaccines to I.R.I.'s injury (*see* Tr. at 33) has many missing links. Finally, there is no evidence regarding a medically appropriate temporal interval between these vaccinations and onset of any injury. Thus, petitioners have failed to demonstrate any basis on which to award compensation, much less that they are entitled to judgment as a matter of law. Summary judgment in favor of petitioners is, therefore, inappropriate.

B. Ruling on the Record.

The failure to establish entitlement to summary judgment does not result in a dismissal of petitioners' claim. However, in view of their refusal to file additional evidence, I will treat their assertion that they have established entitlement to compensation as a request to rule on the record.

1. Legal Standards.

The Vaccine Act requires that the Vaccine Rules provide "the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations cross examinations, or hearings." § 12(d)(2)(D). Thus, a special master "may decide a case on the basis of written submissions without conducting an evidentiary hearing." Vaccine Rule 8(d). Treating petitioners' assertion that the record establishes their entitlement to compensation as a request that I rule on the record as it

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[62] In their petition, Mr. Padmanabhan and Ms. Srinivas claimed that the set of vaccines their son received in March 2008 "significantly aggravated his preexisting mitochondrial disease resulting over time to several disorders" including "[e]ncephalopathy, [i]mmune [d]ysfunction, [f]requent exposure to microbial infection, [o]xidative [s]tress, [i]nflammation of the [b]rain, [n]utritional disorders, and [m]etabolic disorders." They do not advance a theory explaining how the specific vaccines I.R.I. received are capable of causing such injuries. Petitioners came somewhat closer to enunciating their causation theory in their January 2014 filing, which included a "list of published medical research that proves causation of Petitioners encephapathy [*sic*] was in fact caused as a result of vaccines in March 2008 that led further to Autism Diagnosis… Encephapathy [*sic*] causing Autistic symptoms is a well known and understood. Reviewing research below and the medical record clearly proves by a preponderance of evidence…that vaccines caused petitioner's injury." Pet. Resp., filed Jan. 17, 2014, at 6. I note that, even after I gave petitioners detailed instructions about how to file journal articles into the record, they declined to file the articles that they listed, none of which appeared to discuss a causal link between vaccines and either mitochondrial or SCAD disorders. It was not until oral arguments that Mr. Padmanabhan explained his causation theory. He stated that "the vaccine [received on or about March 13, 2008] caused distress" which "resulted in mitochondrial dysfunction… and that resulted in immune dysfunction… [a]nd that caused inflammation" which "resulted in… hypoxia in the brain," which in turn "caused his encephalopathy." Tr. at 33.

now stands, I find that petitioners have failed to muster preponderant evidence of vaccine causation.

In ruling on the record, a special master may decide controverted questions of fact and make conclusions of law. *See* Vaccine Rule 8(d). Congress has instructed special masters to "be vigorous and diligent in investigating factual elements necessary to determine the validity of the petitioner's claim." H.R. REP. No. 99-908, at 17 (1986), *reprinted in* 1986 U.S.C.A.N. 6344, 6358.

There are two ways to establish entitlement to compensation under the Vaccine Act's no-fault system. First, petitioners may demonstrate that I.R.I. suffered a vaccine-specific injury listed on the Vaccine Injury Table within the requisite time period set forth in the Table (a "Table injury"). To prove a Table injury, petitioners must show that the first symptom or manifestation of the onset…of any such illness, disability, injury, or condition…occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." *Shalala v. Whitecotton,* 514 U.S. 268, 270 (1995) (quoting 42 U.S.C. § 11(c)(1)(C)(i)). In such cases, causation is presumed. *See* 42 C.F.R. § 100.3.

Second, petitioners may demonstrate by preponderant and reliable evidence that an injury was caused in fact or significantly aggravated by a vaccine listed on the Table ("actual causation" or "causation-in-fact" or "significant aggravation"). *See* § 11(c)(1)(C); *see also Moberly v. Sec'y, HHS,* 592 F.3d 1315, 1321 (Fed. Cir. 2010) (causation in fact claims); *W.C. v. Sec'y, HHS,* 704 F.3d 1352, 1357 (Fed. Cir. 2013); *Loving v. Sec'y, HHS,* 86 Fed. Cl. 135, 144 (2009); *Hennessey,* 2009 WL 1709053 at *40.

To prove actual causation, petitioners must demonstrate by preponderant evidence "(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." *Althen v. Sec'y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see also Grant v. Sec'y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992); *Hines v. Sec'y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *de Bazan v. Sec'y, HHS*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); *Caves v. Sec'y, HHS,* 100 Fed. Cl. 119, 132 (2011), *aff'd per curiam*, 463 Fed. Appx. 932, 2012 WL 858402 (Fed. Cir. 2012) (holding that each *Althen* factor must be established by preponderant evidence). The applicable level of proof is the "traditional tort standard of 'preponderant evidence.'" *Moberly*, 592 F.3d at 1322 (citing *de Bazan*, 539 F.3d at 1351; *Pafford v. Sec'y, HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Capizzano v. Sec'y, HHS*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *Althen,* 418 F.3d at 1278).

To prove significant aggravation, petitioners must establish the three *Althen* factors, plus demonstrate by preponderant evidence: (1) the vaccinee's condition prior to the vaccination; (2) the condition after the vaccination; and (3) that a comparison of the two conditions constitutes a significant change for the worse after vaccination. *W.C.,* 704 F.3d at 1357 (adopting the six-factor test established in *Loving*); *see also*

Hennessey, 2009 WL 1709053, at *40. A significant aggravation is "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by a serious deterioration in health." § 300aa-33(4).

2. Table Encephalopathy.

The Vaccine Injury Table includes "encephalopathy" as an associated injury (Table injury) for both the DTaP and MMR vaccines. Onset of the first symptom of the encephalopathy must occur within 72 hours following a DTaP vaccination and within 5-15 days of an MMR vaccination. 42 CFR §§ 100.3(a)(II)(B) (DTaP); 100.3(a)(III)(B) (MMR). The other two vaccines received by I.R.I. at the 15 month well child visit (Hib and varicella) do not have any associated Table injuries. 42 C.F.R. § 100.3(a)(IX) (Hib); § 100.3(a)(X) (varicella).

To prove a Table encephalopathy, petitioners have the burden to show that I.R.I. suffered an encephalopathy "and the first symptom or manifestation of the onset…of any such illness, disability, injury, or condition…occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." *Shalala,* 514 U.S. at 270 (quoting § 300aa—11(c)(1)(C)(i)).

However, none of the medical records suggest that I.R.I. experienced any difficulty within either time frame after vaccination. Although petitioners assert that they telephonically reported a fever with hardness and swelling at the injection site after the 15 month vaccinations, there is no evidence that they did so. More significantly, fever and hardness, and swelling at an injection site are not symptoms of a Table encephalopathy.

A Table encephalopathy occurs when an acute encephalopathy is followed by a chronic encephalopathy which lasts for "more than 6 months beyond the date of vaccination." 42 C.F.R. § 100.3(b)(2). An acute encephalopathy is one that is "sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)" and "is indicated by a 'significantly decreased level of consciousness' lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i). A "significantly decreased level of consciousness" occurs when at least one of the following symptoms arises for a period of at least 24 hours:

> (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

42 C.F.R. § 100.3(b)(2)(i)(D).

Petitioners have made several claims that I.R.I. suffered an encephalopathy. *See, e.g.,* Petitioners' Filing, January 17, 2014, at 5. Although there is laboratory evidence that I.R.I. has a mild diffuse encephalopathy, there is no evidence that this encephalopathy meets the requirements for a "Table" encephalopathy, much less that it began during the time frames for onset set forth in the Table. Most significantly, I.R.I. was seen by one of his regular pediatricians three weeks after the allegedly causal vaccinations. At this visit, there were no reports of any symptoms consistent with an acute encephalopathy and no indication by the physician that I.R.I. was displaying symptoms consistent with a chronic encephalopathy. On April 30, 2008, I.R.I.'s pediatrician described him as alert and in no apparent distress, descriptions utterly incompatible with a chronic Table encephalopathy.[63]

In short, petitioners have failed to demonstrate that I.R.I. suffered a Table encephalopathy after the allegedly causal vaccinations. Because their Table injury argument is unpersuasive, petitioners can prevail only by demonstrating that a vaccine or vaccines actually caused or significantly aggravated I.R.I.'s condition. I next turn to their causation in fact claim.

3. Actual Causation.

To establish causation in an off-Table case, petitioners must demonstrate by preponderant evidence that the vaccine caused 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 proximate temporal relationship between vaccination and injury." *Althen* 418 F.3d at 1278. The preponderance standard "requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring) (internal quotation and citation omitted).

A petitioner is not required to establish identification and proof of specific biological mechanisms, as "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280. The petitioner does not have to show that the vaccination was the sole cause, or even the predominant cause, of the injury or condition; showing that the vaccination was a "substantial factor"[64] and a

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[63] There is also a problem with the facts as petitioners allege them. If I.R.I. has an inborn error of metabolism (SCAD being such a disorder), any encephalopathy might well be considered a "metabolic encephalopathy," and therefore one excluded by the Vaccine Injury Table. 42 C.F.R. § 100.3(b)(2)(iii).

[64] The Restatement (Third) of Torts has eliminated "substantial factor" in the factual cause analysis. § 26 cmt. j (2010). Because the Federal Circuit has held that the causation analysis in Restatement (Second) of Torts applies to off-Table Vaccine Act cases (*see Walther v. Sec'y, HHS*, 485 F.3d 1146, 1151 (Fed. Cir. 2007); *Shyface v. Sec'y, HHS,* 165 F.3d 1344, 1352 (Fed. Cir. 1999), this change does not affect the determination of legal cause in Vaccine Act cases: whether the vaccination is a "substantial factor" is still a consideration in determining whether it is the legal cause of an injury. *See Stone v. Sec'y, HHS,* 676

"but for" cause of the injury are sufficient for recovery. *Shyface v. Sec'y, HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999); *see also Pafford,* 451 F.3d at 1355 (petitioner must establish that a vaccination was a substantial factor and that harm would not have occurred in the absence of vaccination).

Although a petitioner cannot be required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect,"[65] when a party files medical literature, a special master may weigh and evaluate that medical literature. When the filed literature fails to support the medical theory alleged, it can be an important factor in determining whether petitioner has met her burden to show vaccine causation.

Causation is determined on a case by case basis, with "no hard and fast *per se* scientific or medical rules." *Knudsen v. Sec'y*, *HHS,* 35 F.3d 543, 548 (Fed. Cir. 1994). Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280; *but see Knudsen*, 35 F.3d at 550 (when evidence is in equipoise, the party with the burden of proof fails to meet that burden).

Althen requires that a petitioner in an off-Table causation case present a reliable medical theory by which a vaccine can cause the injury in question. *Althen*, 418 F.3d at 1278. This first prong of *Althen's* three-part causation test has also been characterized as the equivalent of the "Can it cause?" inquiry used in toxic tort litigation. *See Pafford v. Sec'y, HHS*, No. 01-165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). The medical theory must be a reputable one, although it need only be "legally probable, not medically or scientifically certain." *Knudsen,* 35 F.3d at 548-49. Theories of causation must be reliable as well. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993); *Moberly,* 592 F.3d at 1324.

Althen's second prong requires a logical sequence of cause and effect between the vaccine and the injury. It has been characterized as addressing the "Did it cause?" or specific causation query. *See Pafford*, 2004 WL 1717359, at *4. Circumstantial evidence and medical opinions may be sufficient to satisfy this requirement. *Capizzano*, 440 F.3d at 1325-26. Opinions of treating physicians may also provide the logical connection. *See Andreu v. Sec'y, HHS*, 569 F.3d 1367, 1376 (Fed. Cir. 2009); *see also Moberly,* 592 F.3d at 1323; *Capizzano*, 440 F.3d at 1326.

F.3d 1373, 1379 (Fed. Cir. 2012) ("[T]he causation standard in off-Table Vaccine Act cases is to be applied consistently with the principles set forth in the Second Restatement of Torts.").

[65] *Capizzano v. Sec'y, HHS,* 440 F.3d 1317, 1325 (Fed. Cir. 2006).

The third *Althen* factor requires a proximate temporal relationship between the allegedly causal vaccine and the injury suffered. The requirement of temporal connection necessitates a showing that the injury occurred in a medically or scientifically reasonable period after the vaccination, not too soon (*see de Bazan*, 539 F.3d at 1352) and not too late (*see Pafford*, 451 F.3d at 1358). Merely showing a temporal connection between a vaccination and an injury is insufficient, standing alone, to establish causation. *Grant*, 956 F.2d at 1148. A temporal relationship, even when coupled with the absence of any other identified cause for the injury, is not enough to demonstrate probable cause under the Vaccine Act's preponderance standard. *Moberly*, 592 F.3d at 1323 (citing *Althen*, 418 F.3d at 1278).

a. Althen Prong 1.

Petitioners never articulated a coherent theory about how vaccines caused their son's condition. After reviewing all of the records filed, the transcript, and recorded status conferences, I deduce that petitioners believe that I.R.I.'s DTaP vaccination interacted with an underlying mitochondrial disorder, causing an immune reaction. Tr. at 18-19. This immune reaction then detrimentally interacted with I.R.I.'s MMR vaccine, which in turn caused hypoxia of the brain. Tr. at 19, 33. This hypoxia then caused an encephalopathy, resulting in I.R.I.'s developmental disorders. Tr. at 13, 33. In Mr. Padmanabhan's words, the rash that I.R.I. experienced four weeks after the vaccines in question "is obviously his immune system being haywire, trying to fight the live viruses that were injected to him. And because of his SCAD ailment and possibly his metabolic or mitochondrial dysfunction at this time, he was not able to, and he had either rubella that was—he was fighting from the vaccine and it was causing all the other clinical symptoms like fever, cough and congestions, and—and that was getting worse." *Id.* at 31. Devoid of any supporting scientific evidence, petitioners' theory appears to be that since I.R.I.'s medical condition worsened after his March 2008 vaccines, they must be related to his ailments. This theory confuses timing with causation.

There is simply no evidence—no opinion by a treating physician, no opinion by an expert, and no medical literature—supporting a theory that the DTaP vaccine can interact with an underlying mitochondrial disorder to cause an immune reaction. The record is devoid of evidence that an immune reaction, coupled with an MMR vaccination, can induce hypoxia, or that hypoxia leads to encephalopathy, and in particular to the mild, diffuse encephalopathy I.R.I.'s MRI showed.

Absent "clear, definitive medical records" establishing vaccine causation of the injury in question, an expert medical opinion is necessary to establish a reputable causation theory. *Keith v. Sec'y, HHS*, 55 Fed. Cl. 791, 797 (Fed. Cl. 2003) (citing *Dickerson v. Sec'y, HHS*, 35 Fed. Cl. 593, 599-600 (Fed. Cl. 1996)). In *Keith,* 55 Fed. Cl. at 797, the court affirmed a special master's dismissal of a claim of causation without a medical expert's opinion; *Dickerson,* 35 Fed. Cl. at 599 (citing *Thornton v. Sec'y, HHS,* 35 Fed. Cl. 432, 440-42 (1996) (stating "the firm requirement that medical opinion evidence is still necessary" even in on-Table claims of causation)).

In summary, without an expert opinion, petitioners cannot demonstrate that I.R.I.'s condition, whatever it may be, is vaccine caused. *See Althen,* 418 F.3d at 1278 ("A persuasive medical theory is demonstrated by 'proof of a logical sequence of cause and effect'…supported by 'reputable medical or scientific explanation [,]' i.e., 'evidence in the form of scientific studies or expert medical testimony.'") (*quoting Grant,* 956 F.2d at 1148). The records that have been filed do not present a definitive diagnosis of a mitochondrial disorder, nor is there any evidence linking this alleged disorder and I.R.I.'s childhood vaccines to his ASD. By failing to submit complete medical records and an expert medical opinion, petitioners are unable to meet the first prong of *Althen*.

While some petitioners in the Vaccine Program have argued, with limited success, that *Althen*'s prong one analysis only requires petitioners to provide a "biologically plausible medical theory," *see Doe 93 v. Sec'y, HHS,* 98 Fed. Cl. 553, 566-67 (2011), the Federal Circuit has required petitioners to prove all three prongs "by a preponderance of the evidence." *Koehn v. Sec'y, HHS,* 773 F.3d 1239, 1241-42 (Fed. Cir. 2014). In doing so, the court endorsed the preponderance standard articulated in *Caves v. Sec'y, HHS,* 100 Fed. Cl. 119, 144 (2011); *aff'd without opinion,* 463 Fed. Appx. 932 (Fed. Cir. 2012). In this case, petitioners have fallen far short of establishing prong one by preponderant evidence. Indeed, given the absence of a coherent medical theory, petitioners are unable to meet their burden under any standard.

b. *Althen* Prong 2.

Althen's second prong requires petitioners to establish "specific causation." But because I.R.I.'s parents have been unable to establish that their son's vaccines are logically capable of causing his condition, they cannot possibly demonstrate that the allegedly causal vaccines did in fact cause their son's condition. A claim cannot succeed after it has failed *Althen*'s first prong. *See Verzyer v. Sec'y, HHS,* 100 Fed.Cl. 344, 353 (Fed.Cl. 2011), *aff'd without opinion,* 475 Fed. Appx. 765 (Fed. Cir. 2012); *see also Caves,* 100 Fed. Cl. 144; *aff'd without opinion,* 463 Fed. Appx. 932.

The second *Althen* prong addresses the evidence showing a logical connection between the theory and the injury. Assuming arguendo that stringing vaccines, mitochondrial dysfunction, immune reaction, hypoxia, and encephalopathy together constitutes a reliable theory explaining how vaccines can cause the autistic-like symptoms and autism diagnosis clearly established in this record, petitioners have failed to show the predicate facts that would place their son's clinical picture within the ambit of this theory.

I.R.I. received both of the vaccines in question. However, demonstrating that I.R.I. experienced a rash three weeks after the vaccinations does not show that his immune system was compromised by them. His pediatrician called the rash and illness a "viral syndrome" and possible gastroenteritis. He recovered from the illness and

actually gained language and other skills between the 15 month vaccinations and his 18 month well child visit.

There is no evidence in this record that I.R.I. suffered hypoxia or that hypoxia is somehow responsible for the diffuse, mild encephalopathy found on the 2011 MRI. Moreover, there is no evidence that the encephalopathy occurred at any particular time.

None of his pediatricians noted anything unusual in the type or number of infections he experienced after the allegedly causal vaccinations. Although it appears to me to be quite unlikely that I.R.I. actually has a dysfunctional immune system, accepting Dr. Goldberg's diagnosis at face value, I find no evidence of any connection between immune dysfunction and the symptoms I.R.I. displayed.

Even if I.R.I. actually has SCAD, there is no evidence that vaccines can cause or trigger its onset, and there is some evidence that SCAD alone could account for I.R.I.'s clinical symptoms. I note that SCAD is an inborn error of metabolism. In other words, if I.R.I. has a SCAD deficiency, he was born with it, even if the dysfunction it caused did not begin for many months after his birth.

The evidence that I.R.I. actually has a primary mitochondrial disorder is very scant. Although fatty acid oxidation disorders like SCAD may produce some impairment in mitochondrial function, this dysfunction is classified as a secondary disorder. The Haas article (Court Ex. I) indicates that regression and loss of skills may occur in a primary mitochondrial disorder, but there is no contemporaneous evidence that I.R.I. experienced any regression or loss of skills within six months of the allegedly causal vaccinations.

c. *Althen* prong 3.

Having failed to establish *Althen's* first two prongs, petitioners cannot satisfy the third. Petitioners are unable to show a "proximate temporal relationship between the vaccination and the injury." *Althen,* 418 F.3d at 1278. Petitioners have shown neither a logical nor a specific link between I.R.I.'s vaccines and his condition. Given the evidence presented, it is impossible to establish a proximate and medically appropriate temporal connection between the DTaP, MMR, and Hib vaccines I.R.I. received in March 2008 and onset of his autism symptoms.

4. Conclusions on Actual Causation Theory.

To summarize, petitioners deny that I.R.I. has ASD, in spite of the diagnosis by specialists in the field and observations by other physicians that he appears to be "on the spectrum." Instead they assert that he has a mitochondrial or metabolic disorder, but have failed to file any records reflecting either diagnosis. Their causation theory is confused, relies on facts not in evidence, and is unsupported by the opinion of any expert or even by a treating physician. I cannot accept petitioners' second hand

assertions that one or more of I.R.I.'s physicians supports their causation theory as reliable evidence. Thus, petitioners have not satisfied any of *Althen's* requirements, and have failed to establish their off-Table causation claim.

5. Significant Aggravation.

A significant aggravation is defined as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by a serious deterioration in health." 42 U.S.C. § 300aa-33(4). To prevail under a significant aggravation theory, petitioners must establish, in addition to the *Althen* factors, preponderant evidence of: (1) the vaccinee's condition prior to administration of the vaccine; (2) the vaccinee's current condition or condition following the vaccine; and (3) whether the comparison of the two conditions constitutes a significant aggravation of the person's condition. *Loving,* 86 Fed. Cl. at 144. Because petitioners have failed to establish any of the *Althen* factors by preponderant evidence, they have failed to meet three of the prongs of the *Loving* six-factor test. Nevertheless, I briefly discuss the significant aggravation aspect of their claim because it illustrates the impact of their refusal to file updated medical records.

Petitioners' significant aggravation theory is also entirely unsubstantiated by the record. In their petition, I.R.I.'s parents claim that the vaccines he received significantly aggravated an underlying mitochondrial disorder. Since petitioners have not established that their son suffers from the condition alleged in the petition, I cannot find it was significantly aggravated by a vaccination.

Petitioners have filed sufficient evidence to determine I.R.I.'s condition before the vaccine, but they have repeatedly refused to file any medical records from the last three years, thus precluding me from determining his current condition or adequately comparing his current and past conditions. Comparing I.R.I.'s condition in the six months before and after the vaccination, I cannot conclude that I.R.I was *significantly* worse. Determining if he is significantly worse today is impossible.

Significantly, petitioners did not report any concerns about I.R.I.'s development until his two year well child visit, eight months after the allegedly causal vaccinations. They reported "licking" and slower social communication development, but did not indicate when these symptoms were first observed. They later reported some concerns about I.R.I.'s development at around the time of his sister's birth, when I.R.I. was about 18 months old. They specifically denied any symptoms following his 15 month vaccinations as late as six months before the petition was filed in this case.

VI. Conclusion.

I have no doubt of petitioners' love for I.R.I. Nor do I doubt that they have pursued treatments that they believe are in his best interest. Their belief that I.R.I. has

a mitochondrial disorder, a SCAD deficiency, and immune dysfunction was apparent in their filings and in the oral argument. Their belief that I.R.I.'s condition is vaccine caused is, no doubt, also sincere, but the facts do not support a Table injury, a causation in fact, or a significant aggravation claim. They have firm, fixed beliefs that the Vaccine Program was designed to compensate them based on the evidence they have been willing to produce. However, their beliefs constitute neither the evidence necessary to prevail nor the law that I must apply.

For the reasons stated above, I dismiss this case for failure to prosecute. Alternatively, I find that petitioners have not established preponderant evidence of a Table encephalopathy. Petitioners have also not demonstrated by preponderant evidence that vaccines caused or significantly aggravated their son's condition. Having failed to demonstrate that the vaccines I.R.I received on March 13, 2008 are in any way responsible for his condition, petitioners are not entitled to compensation.

The petition for compensation is therefore DENIED. The clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

Denise K. Vowell
Chief Special Master