No. 19-____

IN THE
Supreme Court of the United States

W.R. III, A MINOR, BY AND THROUGH HIS PARENTS AND NEXT FRIENDS, HEATHER ROGERO and WALTER ROGERO II,

Petitioner - Appellant,

v.

ALEX AZAR II,
SECY. OF HEALTH & HUMAN SERVICES
Respondent- Appellee.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

APPENDIX TO PETITION FOR A WRIT OF CERTIORARI A-H

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APPENDIX A

United States Court of Appeals
for the Federal Circuit

HEATHER ROGERO, WALTER A. ROGERO, II,
W.R., A MINOR, Petitioners-Appellants

v.

SECRETARY OF HEALTH AND HUMAN
SERVICES, Respondent-Appellee

2018-1684

Appeal from the United States Court of Federal Claims in No. 1:11-vv-00770-EDK, Judge Elaine Kaplan.

Decided: September 12, 2018

HEATHER ROGERO, WALTER A. ROGERO, II, W.R., Mountain Home, AR, pro se.

VORIS EDWARD JOHNSON, JR., Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent-appellee. Also represented by C. SALVATORE D'ALESSIO, CATHARINE E. REEVES, CHAD A. READLER

APPENDIX
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Before DYK, LINN, and TARANTO, Circuit Judges. PER CURIAM.

Heather Rogero and Walter Rogero, II, the parents of W.R., a minor, filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986, codified as amended at 42 U.S.C. §§ 300aa-1 to -34. They alleged that W.R. suffered injuries, including encephalopathy, caused at least in part by vaccinations that he received before his second birthday. The special master denied compensation, and the United States Court of Federal Claims affirmed. Because the Court of Federal Claims correctly concluded that the special master's decision was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, we affirm.

I

A

Born in September 2008, W.R. received vaccinations on six occasions before his second birthday. *Special Master Decision* at 15–21.[1] *First*: On November 19, 2008, when he was roughly two months old, W.R. received Pediarix, which includes "the diphtheria/tetanus/pertussis (DTaP), hepatitis B, and inactivated polio vaccines), Hib (Haemophilus influenza type B), and pneumococcal vaccination." Id. at 15. *Second:* He received Pediarix and pneumococcal vaccinations at his four-month well-visit on January 19, 2009. Id. at 15–16. *Third:* He again received Pediarix and pneumococcal vaccinations on April 27, 2009. Id. at 17. *Fourth:* At about eleven months of age on August 1, 2009, W.R. received a Hib

[1] The special master's decision appears at *Rogero v. HHS*, No. 11-770V, 2017 WL 4277580 (Fed. Cl. Sept. 1, 2017). In citing the opinion, we use the pagination as it was released, not Westlaw pagination.

vaccination. Id. at 18. *Fifth*: On September 24, 2009, he received additional vaccinations, which the medical records suggest were a Hepatitis A vaccine and either a Hib or a varicella vaccine. Id. at 18–19. *Sixth*: More than seven months later, on May 4, 2010, W.R. received a DTaP vaccine. Id. at 20.

Thus, five of the six vaccinations occurred before the end of 2009. Until the end of 2009, when the family moved, W.R.'s main doctor was Christopher Dalton, D.O., though W.R. saw other medical service providers. The sixth vaccination—when he was given his fourth DTaP vaccine, which the Rogeros have emphasized in this court—occurred in May 2010. By then he was seeing other providers.

According to the medical records of 2008 and 2009, on the same day as his first vaccinations, W.R. missed the developmental milestone of "turns head to sound." Id. at 15. At four months of age, he missed the "rolling" milestone, and his medical records do not report rolling until he was about eight months old. Id. at 15–17. At five months old, on February 13, 2009, he was diagnosed as underweight and failing to thrive. On March 11, 2009, he was referred to SoonerStart, an early intervention developmental therapy program. Id. at 16. At his nine-month checkup, on June 16, 2009, W.R. was recorded as missing most of his developmental milestones. He "was assessed as being underweight, having short stature, and as being 'off on his development and delayed.'" Id. at 17. Although he made some improvement and had several appointments with

SoonerStart throughout the summer, he again missed most of his developmental milestones at his one-year checkup on September 24, 2009. Id. at 17–18.

The medical records from before 2010 also report other medical issues. W.R. was assessed as having "bad cradle cap" (November 19, 2008), episodes of congestion (November 19, 2008; January 3, 2009), discharge from his eyes (December 3, 2008), and infantile eczema (December 3, 2008; February 13, 2009; and April 27, 2009). *Id.* at 15–19. By the time he was four months old, W.R. had started "having problems of spitting up after eating and while lying down for a diaper change." Id. at 15. He had multiple ear infections in 2009, one in early March and a second in mid-April; he went to the hospital on March 2, 2009 for bronchiolitis; he had allergic reactions, including an episode of hives that resulted in an urgent care visit on April 25, 2009; and he was regularly deemed underweight. Id. at 16–18.

On December 18, 2009, Dr. Dalton assessed W.R. as "essentially behind with fine motor skills and language development," and he recommended aggressive speech and physical therapy. *Id.* at 19. After W.R.'s family moved, W.R. received his sixth vaccination—on May 4, 2010, at his appointment with Barbara Stevens, M.D. W.R. had a follow-up appointment with Dr. Stevens three days later, and the record of that visit contains no report of regression or any negative symptoms. *Id.* at 20.

On June 8 and 15, 2010, W.R. was evaluated by a developmental pediatrician. The notes from the evaluation state that W.R. "meets the DSM [Diagnostic and Statistical Manual] criteria for Autism," but that the pediatrician was deferring adoption of the diagnostic label until W.R.'s second birthday, "even though the literature indicates that the presence of these significant findings is likely to be consistent." Id. at 21–22.

In late June 2010, W.R. saw Dr. Stevens for rhinorrhea and constipation. The Special Master summarized the records from Dr. Stevens: "Among other things, those records from Dr. Stevens reflect a description of W.R. as a 21-month-old boy with failure-to-thrive and autism." *Id.* at 20.

Shortly thereafter, W.R.'s parents changed his primary care provider. While meeting in July 2010 with a pediatrician at the new provider, Mrs. Rogero asked about "mercury poisoning" and speculated about potential causes of W.R.'s autism. *Id.* at 20 n.33. In late July 2010, W.R. went to the emergency room and was assessed as having an allergic reaction. In September 2010, W.R. visited the emergency room and was assessed as having an acute upper respiratory infection. *Id.* at 21.

Between June and September 2010, W.R. saw a number of specialists. In addition to the developmental pediatrician (noted above), W.R. also saw an allergist, several neurologists, a cardiologist, and a gastroenterologist. In particular, W.R. saw neurologist Lucy Civitello, M.D., in late September. The records report an "admitting diagnosis" of "[e]ncephalopathy NOS [not otherwise specified]" and Mrs. Rogero's statements about W.R.'s diagnoses of autism and eczema as well as her assertion that he was possibly injured by aluminum-based vaccines. *Id.* at 21– 23.

On October 25, 2010, W.R. underwent a 23-hour EEG study. No seizure activity was seen on the test, and W.R.'s results were "within normal limits." *Id.* at 23. W.R.'s subsequent medical records indicate that he has "continued to suffer from an autism spectrum disorder, developmental delays, and other medical conditions." *Id.* at 24

B

Acting pro se, Heather and Walter Rogero (the Rogeros) filed a petition for compensation on W.R.'s behalf on November 15, 2011. They ultimately retained counsel, and the case was assigned to a special master under 42 U.S.C. §§ 300aa-12(c)(1), 300aa-12(d)(3)(A). The special master received medical records, medical and other literature, and the testimony of numerous experts on both sides. The Rogeros sought to prove that the aluminum in vaccines received by W.R. can cause "neurodevelopmental disorders, such as encephalopathy or autistic symptoms," *Special Master Decision* at 68, and did so in W.R.'s case.

On September 1, 2017, the special master filed his decision. He rejected the Rogeros' evidence as unpersuasive for various reasons. He denied compensation, finding that the Rogeros had not proved causation under the applicable standards of 42 U.S.C. §§ 300aa-11(c)(1)(C), 300aa-14 and 42 C.F.R. § 100.3, as interpreted by this court in cases such as *Althen* v. HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005), *Pafford* v. HHS, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006), and *Moberly* v. HHS, 592 F.3d 1315, 1322 (Fed. Cir. 2010). *See also LaLonde* v. HHS, 746 F.3d 1334, 1341 (Fed. Cir. 2014). He noted the variety of causation theories presented by the Rogeros' evidence and concluded: "After thoroughly reviewing the record of this case, I have found all of the causation theories advanced in this case to be quite *unpersuasive*." *Special Master Decision* at 47; *see id.* at 82–83.

In so finding, the special master explained that the Rogeros' experts based their causation opinions in key respects on "facts alleged by W.R.'s parents" that "d[id] not appear in W.R.'s contemporaneous medical records." Id.

at 48 (emphasis omitted). He found that the contemporaneous records were "more reliable" than the parental testimony, which he found to be unreliable. Id. Because the expert testimony was based on assertions of fact that did not appear in the medical records, the special master determined that the Rogeros' experts had relied on "critical misassumptions of fact" in forming their opinions, rendering the opinions "fatally flawed" and "wholly unreliable." Id. (emphasis omitted); see *id.* at 49–57.

The special master also found that the qualifications of the government's experts were "*overwhelmingly superior*" to those of the Rogeros' experts and, in addition, were "*far more persuasive*" in the content of their testimony than were the Rogeros' experts. *Id.* at 48; *see id.* at 57–68.

In particular, he found that the Rogeros' experts "failed to demonstrate the *basic premise* of their causation arguments, that the tiny amount of *aluminum* in vaccination *can* cause any harm to vaccinees" or "that the aluminum in W.R.'s *own* vaccines caused him to suffer an 'encephalopathy,' caused his autism spectrum disorder, or caused any other harm." *Id.* at 48; *see id.* at 68–70. Nor did the Rogeros' experts prove the allegations that W.R. had an immune system disorder or a mitochondrial disorder or was more susceptible to harm by vaccinations because of his genetic variants. *Id.* at 48–49; see *id.* at 70–76.

For these and other reasons, the special master determined that the Rogeros had demonstrated neither that vaccines could cause injuries of the type W.R. suffered nor that W.R.'s vaccinations had caused his specific

injuries. Therefore, he determined that the Rogeros were not entitled to Vaccine Act compensation. *Id.* at 85.

On October 2, 2017, the Rogeros timely sought review of the special master's decision in the Court of Federal Claims pursuant to 42 U.S.C. § 300aa-12(e). That court sustained the special master's decision on January 11, 2018, J.A. 323–33, and the judgment was entered the next day, J.A. 740.

On March 8, 2018, within the 60 days permitted by 42 U.S.C. § 300aa–12(f), the Rogeros appealed to this court. They are now acting pro se. We have jurisdiction under 28 U.S.C. § 1295(a)(3).

II

Our task on appeal is to review the special master's decision under the same standard of review that is applied by the Court of Federal Claims. *Milik v. HHS*, 822 F.3d 1367, 1375 (Fed. Cir. 2016). As relevant here, we must uphold the special master's factual findings unless they are arbitrary and capricious. *Id.* at 1376. We have described such review in the Vaccine Act context as "uniquely deferential." Id. If a special master's finding is "based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious." *Id.*

Like all or nearly all Vaccine Act cases, this case involves an individual with undisputed, serious, burdensome, indeed life-altering medical problems. But the Vaccine Act does not provide for compensation of all such conditions. To support compensation under the Vaccine Act in this case, the Rogeros had to establish causation in fact of the asserted injury—specifically, W.R.'s

neurological difficulties. Specifically, they had to show, by a preponderance of the 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 proximate temporal relationship between vaccination and injury. *Althen*, 418 F.3d at 1278. This is not a case subject to the special, less burdensome standards for establishing causation
applicable to certain injuries listed on an official "table" where symptoms appear in a specified time. See 42 U.S.C. § 300aa–14; 42 C.F.R. § 100.3. Although one of the injuries claimed, an "encephalopathy," can be a table injury, *see* 42 C.F.R. § 100.3, there was no allegation and proof in this case that W.R.'s symptoms appeared in the statutorily required time, and so the case was presented and tried under the usual standards requiring proof of causation.

The special master found that the Rogeros' proof failed under all three of the Althen requirements. He found that the proof (1) did not establish that "aluminum adjuvants in vaccines can cause neurological injury," (2) did not establish "that it is 'more probable than not' that W.R.'s vaccinations containing aluminum adjuvants did contribute to the causation of one or more of W.R's own neurologic or autoimmune conditions," and (3) also did not establish "a proximate temporal relationship between the vaccination and the injury." *Special Master Decision at 84* (emphasis omitted). On appeal, we conclude, the Rogeros have not shown that these findings, which followed the established legal standards, were arbitrary and capricious.

The Rogeros' contentions, at bottom, take issue with the special master's interrelated findings that deemed the medical records as to W.R.'s conditions more reliable than the Rogeros' testimony, that credited the government's experts over the Rogeros' experts, and that

accepted the autism diagnosis over some other "encephalopathy" diagnosis. In all of those respects, however, we see no basis for rejecting the special master's findings as arbitrary and capricious.

The special master determined that it was appropriate to "credit the contemporaneous medical records over the assertions" of the Rogeros, whose testimony about conditions he did not find reliable. *Special Master Decision* at 49 (emphasis omitted). Determinations of relative weight of different evidence are generally for the trier of fact. *See Moberly*, 592 F.3d at 1325–26. More particularly, it is a familiar and reasonable assessment that contemporaneous documentary evidence of the sort at issue here, prepared by professionals doing their jobs independently of litigation, can be (though is not necessarily) more reliable than testimony of interested parties. *See Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Reusser v. HHS*, 28 Fed. Cl. 516, 523 (1993) (stating that "written 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"); cf. *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362–63 (Fed. Cir. 2013) (documentary evidence may be more reliable in patent context); *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1350–51 (Fed. Cir. 2001) (documents preferred to corroborate inventor testimony). We see nothing unreasonable about applying that rationale in this particular case.

The special master likewise had a sufficient basis for finding the testimony of the government's

experts more persuasive than that of the Rogeros' experts. That finding rested in part on detailed comparisons of the experts' qualifications. *Special Master Decision* at 57–63. It rested in part on detailed explanations of problems with the content of the testimony of the Rogeros' experts, including problems of inconsistency and inadequate support in medical literature. *Id.* at 63–68.

Perhaps most importantly, the special master's findings rested on the strength of the explanations given by the government's experts, especially as to the deficiencies of key bases for the assertions of the Rogeros' experts. For example, the special master reasonably credited government expert Dr. Edward Cetaruk's explanation that the Rogeros' experts had no sound scientific foundation for finding injury causation from "the tiny amount of aluminum" in the vaccines at issue. *Id.* at 69. Similarly, the special master reasonably credited government expert Dr. Max Wiznitzer's explanation that the contemporaneous medical records "show that W.R.'s development gradually got further and further behind the typical child's development course, *without* a series of *distinct regressions* after each vaccine administration, as some of [the Rogeros'] experts assumed." Id. at 56; *see id.* at 50–56. Likewise, the special master reasonably credited government expert Dr. Andrew MacGinnitie's explanation of why W.R.'s medical records contradicted the assertion that W.R. had abnormal immune reactions to the vaccinations. Id. at 70. With respect to the Rogeros' assertions about genetic variants and mitochondrial dysfunction, the special master examined in detail the weaknesses in the testimony by the Rogeros' experts as shown by the

testimony of the government's experts. Id. at 72–76. The Rogeros have not shown that this analysis—including its repeated demonstration of how the Rogeros' experts relied on factual assumptions not supported by the contemporaneous medical records—was arbitrary and capricious.

The Rogeros also criticize the special master's decision for its crediting of the diagnosis of autism, arguing that it should have focused on "encephalopathy." But as an initial matter, there was a sufficient basis in the record for the special master to accept the autism diagnosis. The medical records, which we have summarized above, support the finding that "W.R.'s medical records show that he has been definitively diagnosed with an autism spectrum disorder." *Id.* at 80.[2] And the government's expert, Dr. Wiznitzer, confirmed the propriety of the diagnosis based on the records and explained the reasons in adequate detail. *See id.* at 45–46, 56, 81 n.68 (recounting testimony).

And in any event, the special master did not limit his focus. He concluded that the Rogeros had "failed to show that the aluminum in vaccines harmed W.R. in any way" and that "the outcome of this case would be no different if W.R. had never been diagnosed with an ASD." *Id.* at 80– 81 (emphasis added). The Rogeros have not shown lack of support for that finding. And that finding makes immaterial their contention that W.R. met diagnostic criteria for "encephalopathy" as defined in the Table and the DSM-IV—neither of which, moreover, was a basis for any cited testimony by the Rogeros' experts.

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[2] It has not been shown that the issues before us are materially affected by any difference between "autism" and (a newer nomenclature) "autistic spectrum disorder," both terms having been used throughout this case.

III

The Rogeros have not shown reversible error—in particular, they have not shown arbitrary and capricious fact finding—in the special master's determination that they failed to show by a preponderance of the evidence that W.R.'s vaccinations caused any of his alleged injuries. Accordingly, we affirm the Court of Federal Claims' decision.

No costs.

AFFIRMED

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

NOTICE OF ENTRY OF
JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED:
09/12/2018

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing en banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

No costs were taxed in this appeal.

Regarding exhibits and visual aids: Your attention is directed Fed. R. App. P. 34(g) which states that the clerk may destroy or dispose of the exhibits if counsel does not reclaim them within a reasonable time after the clerk gives notice to remove them. (The clerk deems a reasonable time to be 15 days from the date the final mandate is issued.)

FOR THE COURT

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

cc: Voris Edward Johnson Jr.
Heather Rogero, Walter Rogero, W.R.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT
717 MADISON PLACE, N.W.
WASHINGTON, D.C. 20439
PETER R. MARKSTEINER CLERK'S OFFICE
CLERK OF COURT 202-275-8000

APPENDIX B

HEATHER ROGERO, WALTER A. ROGERO, 11,

W.R., A MINOR,
Petitioners-Appellants

SECRETARY OF HEALTH AND HUMAN **SERVICES,**

Respondent-Appellee

2018-1684

Appeal from the United States Court of Federal Claims in No. 1:11-vv-00770-EDK, Judge Elaine Kaplan.

ON MOTION

PER CURIAM.

ORDER

Appellants Heather Rogero, Walter A. Rogero, II and W.R. move for judicial notice.

Upon consideration thereof,

IT Is ORDERED THAT: The motion is denied

January 16. 2019
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
FOR THE COURT
Clerk of Court

APPENDIX C

HEATHER ROGERO,
WALTER A. ROGERO, 11,
W.R., A MINOR,
Petitioners-Appellants

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee

2018-1684

Appeal from the United States Court of Federal Claims in No. 1:11-vv-00770-EDK, Judge Elaine Kaplan.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before PROST, Chief Judge, NEWMAN, LOURIE, LINN [1], DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, Circuit Judges.

PER CURIAM.

ORDER
ROGERO v. HHS

Appellants Heather Rogero, Walter A. Rogero, II and W.R. filed a combined petition for panel rehearing and rehearing en banc. A response to the petition was invited by the court and filed by appellee HHS. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT Is ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on January 25, 2019.

FOR THE COURT

January 18. 2019 /s/ Peter R. Marksteiner
Date Peter R. Marksteiner
Clerk of Court

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[1] Circuit Judge Linn participated only in the decision on the petition for panel rehearing

APPENDIX D

United States Court of Appeals for the Federal Circuit

HEATHER ROGERO, WALTER A. ROGERO, II,
W.R., A MINOR,
Petitioners-Appellants
v.
SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee

2018-1684

Appeal from the United States Court of Federal Claims in No. 1:11-vv-00770-EDK, Judge Elaine Kaplan.

ON MOTION

Before DYK, LINN, and TARANTO, *Circuit Judges.*
PER CURIAM.

O R D E R

Upon consideration of appellants' motion to stay execution of the mandate, IT IS ORDERED THAT:

The motion is denied.

January 25, 2019
Date

FOR THE COURT
/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

APPENDIX E

In the United States Court of Federal Claims

No. 11-770 V

HEATHER ROGERO and WALTER A. ROGERO, II, Friends of W.R., a minor

v. **JUDGMENT**

SECRETARY OF THE DEPT. OF HEALTH AND HUMAN SERVICES

Pursuant to the court's Opinion and Order, filed January 11, 2018, denying petitioners' motion for review and affirming the special master's Decision, filed September 1, 2017,

IT IS ORDERED AND ADJUDGED this date, pursuant to Appendix B, Vaccine Rule 30, that the petition is dismissed.

Lisa L. Reyes
Clerk of Court
By: s/ Anthony Curry
Deputy Clerk

January 12, 2018

NOTE: As to election, 90 days from this or the issuance of the appellate court's mandate, see Appendix B, Rule 33.

Represented petitioners' motions for attorneys' fees and costs shall be filed within 180 days of judgment, see Vaccine Rule 13. Pro se petitioners may seek litigation costs within 180 days of judgment.

As to petition for review, 60 days from this date, see Appendix B, Rule 32. Petition for review and filing fee of $505.00 should be mailed to the following address: Clerk, U.S. Court of Appeals for the Federal Circuit, 717 Madison Place, NW, Washington, DC 20439.

APPENDIX F

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 11-770V
(To be published)

HEATHER ROGERO and WALTER A. ROGERO, II, Friends of W.R., *a minor*,	*	Filed: September 1, 2017
Petitioners,	*	
v.	*	~~Autism~~; Vaccine Act Entitlement; Causation-in-fact; Pediarix; Hib; Prevnar; Seborrheic Dermatitis; Encephalopathy; Autoimmune Illnesses; Aluminum Adjuvant
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Clifford J. Shoemaker, Vienna, VA, Virginia, for Petitioners.
Voris Johnson, Department of Justice, Washington, D.C., for Respondent.

DECISION

HASTINGS, *Special Master.*

This is an action in which the Petitioners, Heather and Walter Rogero II, request compensation under the National Vaccine Injury Compensation Program (hereinafter "the Program"[1]), on account of their minor son ("W.R."). Petitioners allege that a series of vaccinations administered to W.R. on November 19, 2008, January 19, 2009, April 27, 2009, August 1, 2009, September 24, 2009, and May 4, 2010, caused a variety of ~~neurodevelopmental~~ and immunological injuries. Among W.R.'s neurodevelopmental conditions, he has been diagnosed with an autism spectrum disorder (ASD). For the reasons set forth below, I conclude that Petitioners are not entitled to an award.[2]

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[1] The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2012 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2012 ed.). The statutory provisions defining the Program are also sometimes referred to as the "Vaccine Act."

[2] Although I have considered the entire record, including the voluminous medical records and medical literature, in arriving at my decision, I will only discuss evidence specifically relevant to resolution of this matter. *See Paterek v. HHS*, 527 Fed. Appx. 875, 884 (Fed. Cir. 2013). This includes medical literature submitted by both sides.

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. §300aa-13(a)(1)(A); §300aa-11(c)(1)(C)(i); §300aa-14(a); §300aa-13(a)(1)(B).

[§300aa-11(c)(1)(C)(ii)(II)
is missing, and an injury "set in the Table" outside the requisite time]

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. §300aa-13(a)(1)(B); §300aa-11(c)(1)(C)(ii). ("Causation-in-fact" is also known as "actual causation.") In such a situation, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination initially caused, or significantly aggravated, the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination initially caused or aggravated the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or aggravation, but must demonstrate that the vaccination was at least a "substantial factor" in causing or aggravating the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" and the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of an expert. (*Id.* at 1279-80.) The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." (*Id.* at 1280.)

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instruction for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program fact-finders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden. The issue of the temporal relationship between vaccination and the onset of an alleged injury was further discussed in *Locane v. HHS*, 685 F.3d 1375 (Fed. Cir. 2012), and *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013). *Moberly v. HHS*, 592 F.3d 1315 (Fed. Cir. 2010), concluded that the "preponderance of the evidence" standard that applies to Vaccine Act cases is the same as the standard used in traditional tort cases, so that *conclusive* proof involving medical literature or epidemiology is *not* needed, but demonstration of causation must be more than "plausible" or "possible." Both *Andreu v. HHS*, 569 F.3d 1367 (Fed. Cir. 2009), and *Porter v. HHS*, 663 F.3d 1242 (Fed. Cir. 2011), considered when a determination concerning an expert's credibility may reasonably affect the outcome of a causation inquiry. *Broekelschen v. HHS*, 618 F.3d 1339 (Fed. Cir. 2010), found that it was appropriate for a special master to determine the reliability of a diagnosis before analyzing the likelihood of vaccine causation. *Lombardi v. HHS*, 656 F.3d 1343 (Fed. Cir. 2011), and *Hibbard v. HHS*, 698 F.3d 1355 (Fed. Cir. 2012), both again explored the importance of assessing the accuracy of the diagnosis that supports a claimant's theory of causation. *Doe 11 v. HHS*, 601 F.3d 1349 (Fed. Cir. 2010) and *Deribeaux v. HHS*, 717 F.3d 1363 (Fed. Cir. 2013), both discuss the burden of proof necessary to establish that a "factor unrelated" to a vaccine may have caused the alleged injury.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the reliability of expert testimony and other scientific evidence relating to causation issues. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is appropriate for special masters to utilize *Daubert*'s factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases.

II

BACKGROUND: THE OMNIBUS AUTISM PROCEEDING ("OAP")

[AUTISM IS NOT AN ALLEGATION OR INJURY IN ROGERO, AND NO MMR RECIEVED]

~~This case is one of more than 5,400 cases filed under the Program in which petitioners alleged that conditions known as "autism" or "autism spectrum disorders" ("ASD")~~[3] were caused by one or more vaccinations. A special proceeding known as the Omnibus Autism Proceeding ("OAP") was developed to manage these cases within the Office of Special Masters ("OSM"). A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in the six entitlement decisions issued as "test cases" for two theories of causation litigated in the OAP (see cases cited below), and will only be summarized here.

A group called the Petitioners' Steering Committee ("PSC") was formed in 2002 by the many attorneys who represented Vaccine Act petitioners who raised autism-related claims. About 180 attorneys participated in the PSC. Their responsibility was to develop any available evidence indicating that vaccines could contribute to causing autism, and eventually present that evidence in a series of "test cases," exploring the issue of whether vaccines could cause autism, and, if so, in what circumstances. Ultimately, the PSC selected groups of attorneys to present evidence in two different sets of "test cases" during many weeks of trial in 2007 and 2008. In the six test cases, the PSC presented two separate theories concerning the causation of ASDs.

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[3] "Autism Spectrum Disorder" is a *general* classification which as of 2010 included five different specific disorders: Autistic Disorder, Childhood Disintegrative Disorder, Asperger's Syndrome, Rett Syndrome, and Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). *King v. HHS*, No. 03-584V, 2009 WL 892296 at *5 (Fed. Cl. Spec. Mstr. Feb. 12, 2010). The term "autism" is often utilized to encompass *all* of the types of disorders falling within the autism spectrum. (*Id.*) I recognize that since the OAP test cases, the consensus description of ASDs, contained now in the "DSM-V" as opposed to the prior "DSM-IV," revises the prior subcategories of ASD set forth in the first sentence of this footnote. However, the DSM-V retains the same *general description* of ASDs. An ASD is a serious form of neurodevelopmental disorder defined by a collection of symptoms and behaviors, including significant impairment of social interaction and language skills, and the presence of repetitive, stereotyped interests. *E.g.*, *Snyder v. HHS*, No. 01-162V, 2009 WL 332044, at *31 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

The first theory alleged that the *measles* portion of the measles, mumps, rubella ("MMR") vaccine could cause ASDs. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that the mercury contained in *thimerosal-containing vaccines* could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC's *first* theory rejected the petitioners' causation theories. *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009) *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd* 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).[4] Decisions in each of the three "test cases" pertaining to the PSC's *second* theory also rejected the petitioners' causation theories, and the petitioners in each of those three cases chose not to appeal. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

The "test case" decisions were comprehensive, analyzing in detail all of the evidence presented on both sides. The three test case decisions concerning the PSC's *first* theory (concerning the MMR vaccine) totaled more than 600 pages of detailed analysis, and were solidly affirmed in many more pages of analysis in three different rulings by three different judges of the United States Court of Federal Claims, and in two rulings by two separate panels of the United States Court of Appeals for the Federal Circuit. The three special master decisions concerning the PSC's *second* theory (concerning vaccinations containing the preservative "thimerosal") were similarly comprehensive.

All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit *unanimously rejected* the petitioners' claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism.

Thus, the proceedings in the six "test cases" concluded in 2010. Thereafter, the Petitioners in this case, and the petitioners in other cases within the OAP, were instructed to decide how to proceed with their own claims. The vast majority of those autism petitioners elected either to withdraw their claims or, more commonly, to request that the special master file a decision denying their claim on the written record, resulting in a decision rejecting the petitioner's claim for lack of support. However, a small minority of the autism petitioners have elected to continue to pursue their cases, seeking other causation theories and/or other expert witnesses. A few such cases have gone to trial before a special master, and in the cases of this type decided thus far, all have resulted in *rejection* of petitioners' claims that vaccines played a role in causing their child's autism. *See, e.g., Henderson v. HHS*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Vowell Sept. 28,

[4] The petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims.

2012) (autism not caused by pneumococcal vaccination); *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *Murphy v. HHS*, No. 05-1063V, 2016 WL 3034047 (Fed. Cl. Spec. Mstr. Corcoran Apr. 25, 2016) (autism not caused by DTaP or MMR vaccines), *aff'd*, 2016 WL 4926207 (Fed. Cl. Aug. 15, 2016); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Hastings Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines); *Long v. HHS*, No. 08-792V, 2015 WL 1011740 (Fed. Cl. Spec. Mstr. Hastings Feb. 19, 2015) (autism not caused by influenza vaccine); *Brook v. HHS*, No. 04-405V, 2015 WL 3799646 (Fed. Cl. Spec. Mstr. Hastings May 14, 2015) (autism not caused by MMR or Varivax vaccines); *Holt v. HHS*, No. 05-136V, 2015 WL 4381588 (Fed. Cl. Spec. Mstr. Vowell June 24, 2015) (autism not caused by hepatitis B vaccine), *aff'd*, 132 Fed. Cl. 194 (2017); *Lehner v. HHS*, No. 08-554V, 2015 WL 5443461 (Fed. Cl. Spec. Mstr. Vowell July 22, 2015) (autism not caused by influenza vaccine); *Miller v. HHS*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Vowell August 18, 2015) (ASD not caused by combination of vaccines); *Allen v HHS*, No. 02-1237V, 2015 WL 6160215 (Fed. Cl. Spec. Mstr. Vowell Sept. 26, 2015) (autism not caused by MMR vaccination); *R.K. v. HHS*, No. 03-632V, 2015 WL 10936124 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2015) (autism not caused by influenza vaccine), *aff'd*, 125 Fed. Cl. 57 (2016), *aff'd*, 2016 WL 7174139 (Fed. Cir. Dec. 9, 2016); *Hardy v. HHS*, No. 08-108V, 2015 WL 7732603 (Fed. Cl. Spec. Mstr. Hastings Nov. 3, 2015) (autism not caused by several vaccines); *Sturdivant v. HHS*, No. 07-788V, 2016 WL 552529 (Fed. Cl. Spec. Mstr. Hastings Jan. 21, 2016) (autism not caused by Hib and Prevnar vaccines); *R.V. v. HHS*, No. 08-504V, 2016 WL 3882519 (Fed. Cl. Spec. Mstr. Corcoran Feb. 19, 2016) (autism not caused by influenza vaccine), *aff'd*, 2016 WL 3647786 (Fed. Cl. June 2, 2016); *Cunningham v. HHS*, No. 13-483V, 2016 WL 4529530 (Fed. Cl. Spec. Mstr. Hastings Aug. 1, 2016) (autism not caused by MMR vaccine), *aff'd*, 2017 WL 1174448 (Fed. Cl. Jan. 25, 2017); *T.M. v. HHS*, No. 08-284V (Fed. Cl. Spec. Mstr. Corcoran Aug. 9, 2016) (not yet published) (autism not caused by DTaP vaccine), *aff'd*, 2017 WL 3184726 (Fed. Cl. June 30, 2017) ; *Anderson v. HHS*, 02-1314V, 2016 WL 8256278 (Fed. Cl. Spec. Mstr. Corcoran Nov. 1, 2016) (autism not caused by MMR vaccination), *aff'd*, 2017 WL 1787975 (Fed. Cl. May 5, 2017).

In addition, some autism causation claims have been rejected *without trial*, at times over the petitioner's objection, in light of the failure of the petitioner to file plausible proof of vaccine-causation. *See, e.g., Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Campbell-Smith Sept. 19, 2012) (autism not caused by MMR vaccination); *Fester v. HHS*, No. 10-243V, 2016 WL 1745436 (Fed. Cl. Spec. Mstr. Dorsey April 7, 2016) (autism not caused by measles, mumps, rubella, and varicella (MMRV) vaccine); *Fresco v. HHS*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Vowell Jan. 7, 2013) (autism not caused by multiple vaccines); *Fesanco v. HHS*, No. 02-1770, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Hastings Nov. 9, 2010) (autism not caused by multiple vaccines); *Miller v. HHS*, No. 06-753V, 2012 WL 12507077 (Fed. Cl. Spec. Mstr. Hastings Sept. 25, 2012) (autism not caused by DTaP or MMR vaccines); *Pietrucha v. HHS*, No. 00-269V, 2014 WL 4538058 (Fed. Cl. Spec. Mstr. Hastings Aug. 22, 2014) (autism not caused by multiple vaccines); *Bushnell v. HHS*, No. 02-1648, 2015 WL 4099824 (Fed. Cl. Spec. Mstr. Hastings June 12, 2015) (autism not caused by multiple vaccines); *Bokmuller v. HHS*, No. 08-573, 2015 WL 4467162 (Fed. Cl. Spec. Mstr. Hastings June 26, 2015) (autism not caused by multiple vaccines); *Canuto v. HHS*, No. 04-1128, 2015 WL 9854939 (Fed. Cl. Spec. Mstr. Hastings Dec. 18, 2015) (autism not caused by DTP and DTaP

vaccines); *Valle v. HHS*, No. 02-220V, 2016 WL 2604782 (Fed. Cl. Spec. Mstr. Hastings April 13, 2016) (autism not caused by DTaP vaccine); *Hooker v. HHS*, 02-472V, 2016 WL 3456435 (Fed. Cl. Spec. Mstr. Hastings May 19, 2016) (autism not caused by multiple vaccines). Judges of this court have affirmed the practice of dismissal without trial in such cases. *E.g.*, *Fesanco v. HHS*, 99 Fed. Cl. 28 (2011) (Judge Braden affirming); *Canuto v. HHS*, No. 04-1128V, 2016 WL 2586510 (Fed. Cl. Apr. 18, 2016) (Judge Yock affirming), *aff'd*, 2016 WL 5746370 (Fed. Cir. Oct. 4, 2016).

In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can contribute to causing autism.[5]

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[5] I am well aware, of course, that during the years since the "test cases" were decided, in two cases involving vaccinees suffering from ASDs, Vaccine Act compensation was granted. But in *neither* of those cases did the Respondent concede, nor did a special master find, that there was any *"causation-in-fact"* connection between a vaccination and the vaccinee's ASD. Instead, in both cases it was conceded or found that the vaccinee displayed the symptoms of a *Table Injury* within the Table time frame after vaccination. (See Section I above).

In *Poling v.* HHS, the presiding special master clarified that the family was compensated because the Respondent conceded that the Poling child had suffered a *Table Injury--not* because the Respondent or the special master had concluded that any vaccination had contributed to causing or aggravating the child's ASD. *See Poling v.* HHS, No. 02-1466V, 2011 WL 678559, at *1 (Fed. Cir Spec. Mstr. Jan. 28, 2011) (a fees decision, but noting specifically that the case was compensated as a Table Injury).

Second, in *Wright v. HHS*, No. 12-423, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015), Special Master Vowell concluded that a child, later diagnosed with ASD, suffered a "Table Injury" after a vaccination. However, she stressed that she was *not* finding that the vaccinee's ASD in that case was "caused-in-fact" by the vaccination--to the contrary, she specifically found that the evidence in that case did *not* support a "causation-in-fact" claim, going so far as to remark that the petitioners' "causation-in-fact" theory in that case was "absurd." *Wright v. HHS*, No. 12-423, 2015 WL 6665600, at *2 (Fed. Cl. Spec. Mstr. Sept. 21, 2015).

The compensation of these two cases, thus, does *not* afford any support to the notion that vaccinations can contribute to the *causation* of autism. In setting up the Vaccine Act compensation system, Congress forthrightly acknowledged that the Table Injury presumptions would result in compensation for some injuries that were *not*, in fact, truly vaccine-caused. H.R. Rept. No. 99-908, 18, 1986 U.S.C.C.A.N. 6344, 6359. ("The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of a vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related.")

III

PROCEDURAL HISTORY OF THIS CASE

A. Petitioners' filing of a pro se Petition

Petitioners filed their claim *pro se* on November 15, 2011. (Original Petition ("Pet."), ECF No. 1.) That petition alleged that due to vaccinations administered to W.R. on November 19, 2008 -- specifically, the Pediarix (combination vaccine comprised of hepatitis B ("Hep B"), inactivated polio ("IPV"), and diphtheria-tetanus-acellular pertussis (DTaP) vaccines), haemophilus influenzae ("Hib"), and pneumococcal conjugate ("PCV") vaccines -- caused the onset of W.R.'s "seborrheic dermatitis, gastroesophageal reflux disease ("GERD"), as well as other auto-immune type illnesses." (Pet., p. 1, parenthesis in original.) This case was originally assigned to my docket at that time. (ECF No. 3.)

Petitioners eventually filed medical records on February 17, 2012 (Exhibits (Exs.) 1-25; ECF No. 9), and on April 12, 2012 (Exs. 26-39; ECF No. 11). On September 14, 2012, Mr. and Mrs. Rogero filed their separate affidavits as a single court filing, marking Mrs. Rogero's affidavit as "Ex. 40" (ECF No. 15, pp. 2-8), and Mr. Rogero's affidavit as "Ex. 41" (*id.*, pp. 9-11). Petitioners filed a status report on December 7, 2012, indicating their belief that all medical records and affidavits were filed in this case, and that the record was ready for Respondent's review. (ECF No. 17.)

B. Respondent's "Rule 4(c) Report" and Motion To Dismiss

On February 1, 2013, Respondent filed a combined "Rule 4(c) Report" and Motion To Dismiss, opposing compensation and moving for the court to dismiss this case. (ECF No. 19.) Petitioners contacted my chambers on March 1, 2013, informing my staff that they were consulting an attorney; thus, I postponed all proceedings until an attorney's appearance was entered in this case. (ECF No. 22.) Petitioners were able to secure attorney representation, with attorney Clifford Shoemaker taking over their case. (ECF No. 20.) This case was then reassigned to the docket of Special Master Nora Beth Dorsey[6] on March 8, 2013. (ECF No. 25.)

Petitioners filed a response to Respondent's "Rule 4(c) Report" and Motion To Dismiss on May 13, 2013. (ECF No. 32.) In that response, Petitioners alleged that a *series of vaccinations*[7] administered to W.R. at various times caused his "multiple autoimmune illnesses."

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[6] Special Master Dorsey became the Chief Special Master of this Court, effective as of September 1, 2015.

[7] Although unclear at first glance, that response seemed to allege, in effect, that a *series* of vaccinations administered on the following dates -- November 19, 2008 (Pediarix, Hib, and pneumococcal vaccines); January 19, 2009 (Pediarix, Prevnar, and Hib vaccines); April 27, 2009 (Hib, Pediarix, and Prevnar vaccines); August 1, 2009 (Hib vaccine); September 24, 2009 (Hib and varicella vaccines); and May 4, 2010 (DTaP vaccine) -- *caused or aggravated* W.R.'s purported injuries. (*See* ECF No. 32, pp. 2-4; 4-7; 7-9; 9-10; 10-12; and 13 (discussion regarding

(*Id.*, p. 43.) Petitioners described those alleged "multiple autoimmune illnesses" into three broad categories comprised of various non-specific injuries, including: (1) "neurological conditions"[8]; (2) "[i]mmunological dysregulation"[9]; and (3) "neuroinflammation/microglial activation and mitochondrial dysfunction"[10] injuries. (*Id.*) Furthermore, on May 13 and 14, 2013, Petitioners refiled certain medical records (Exs. 5 and 18; ECF No. 29),[11] and filed additional medical records and medical literature, representing that those materials supported claims made in their response (Exs. 42-81; ECF Nos. 30-31, 33-35).

On May 20, 2013, Special Master Dorsey denied Respondent's Motion to Dismiss, allowing Petitioners an opportunity to further develop their claims in this case. (ECF No. 36, p. 3.)[12]

W.R.'s administered set of vaccinations starting from November 19, 2008); *see also* ECF No. 32, pp. 43-44.)

[8] That response listed the following "neurological conditions" allegedly suffered by W.R.: "chronic encephalopathy, toxic encephalopathy, developmental delay, oral motor dyspraxia, gross motor delay, hypotonia, sluggish pupillary response, sensory processing deficits, motor planning deficits, severe articulation and expressive language disorder and seizure-like episodes." (ECF No. 32, p. 43.)

[9] Although unclear at first glance, that response seemed to allege that W.R.'s "immunological dysregulation" is "evidenced" by various laboratory testing results. (ECF No. 32, p. 43.) Some of those laboratory testing results listed were: "folate blocking antibodies"; "high platelets"; "antibodies to food, immunologically mediated inflammation to the intestinal mucosa (elevated lysosome)"; and "delayed type (Type IV) hypersensitivity reactions (delayed food allergies IgG)." (*Id.*) Moreover, as further "evidence" of W.R.'s "immunological dysregulation," that response listed other injuries allegedly suffered by W.R., such as: "atopic dermatitis"; "allergic gastritis"; "dermatitis"; "eczema due to immune dysregulation"; in addition to certain other injuries such as: "suggested eosinophilia esophagitis" and "repeat elevated EOS for over two years." (*Id.*)

[10] That response stated that "additional evidence" of W.R.'s "neuroinflammation/microglial activation and mitochondrial dysfunction" included various results of laboratory testing conducted for W.R., purportedly reflecting abnormal results such as: "elevated lactic/pyruvate"; "low Co2"; "elevated vanilamandellate"; "elevated homovanillate and porphyrins"; "high quinolinic acid"; and "high glutamate." (ECF No. 32, p. 43.)

[11] Petitioners represented that they refiled Exs. 5 and 18 due to a scanning error that caused certain double-sided pages to be omitted in the originally-filed exhibits. (ECF No. 29.)

[12] On May 28, 2013, Petitioners filed a motion to redact Special Master Dorsey's ruling denying Respondent's motion to dismiss, requesting various information to be redacted from that ruling. (ECF No. 38.) That motion to redact was denied by Special Master Dorsey on June 28, 2013; however, she issued an order *sua sponte* to: (1) redact W.R.'s name to his initials in the

C. Development of the case

Petitioners submitted various additional materials in support of their claim on September 27, 2013. (ECF Nos. 43-46.) Those filings included: (1) medical records (Exs. 82-85; ECF No. 43); (2) the expert report and *curriculum vitae* of Christopher Shaw, Ph.D. (Exs. 86-87; ECF No. 44); (3) the expert report and *curriculum vitae* of Stephanie Seneff, Ph.D. (Exs. 88-89; ECF No. 45); and (4) supporting medical literature (Exs. 91-98; ECF No. 46).

On October 1, 2013, Petitioners submitted the expert report and *curriculum vitae* of Christopher Exley, Ph.D. (Exs. 99-100; ECF No. 49.) Petitioners filed the expert report of Helen Ratajczak, Ph.D., on October 11, 2013 (Ex. 101, ECF No. 52),[13] and filed her *curriculum vitae* on May 12, 2014 (Ex. 103, ECF No. 63).

On November 21, 2013, Respondent filed a Motion for Clarification of Petitioners' Theory ("Clarification Motion"), stating that the expert reports submitted by Petitioners to that date "postulate a litany of different theories across a host of subject areas ... to explain why [W.R.] has developmental delays, including autism," and that it was unclear at that time as to what "[P]etitioners' theory is or which experts support it." (ECF No. 53, p. 1.) Thus, Respondent requested for Petitioners to clarify their theory of the case, and to specify exactly how that theory was supported by the expert reports filed to that date. (*Id.*, p. 9.)

After several extensions of time, on May 12, 2014, Petitioners filed a response to that Clarification Motion (ECF No. 68), and submitted numerous materials, including: (1) additional medical records (Exs. 102, 121-26; ECF Nos. 63, 67)[14]; (2) the expert report and *curriculum vitae* of Mary Megson, M.D. (Exs. 104-05; ECF No. 64); and (3) additional medical literature (Exs. 106-120; ECF Nos. 65-66). Petitioners' response to that Clarification Motion indicated that Petitioners various experts were providing "multiple theories" of causation (ECF No. 68, p. 1), but stated that "all of the [Petitioners' expert] reports are focusing . . . on the role of aluminum in some of the vaccines" and that "clearly a child who is genetically susceptible is one who has difficulty excreting aluminum, thereby resulting in the aluminum accumulating in the

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ruling denying Respondent's motion to dismiss, and (2) to continue that practice in all future filings. (ECF No. 40, p. 3.)

[13] Petitioners originally filed the expert report of Dr. Ratajczak on September 27, 2013. (*See* Ex. 90; ECF No. 45.) However, on September 30, 2013, Petitioners filed a motion to strike that expert report from the record, representing that the expert report was incomplete as filed. (ECF No. 47.) Special Master Dorsey granted that motion on October 1, 2013. (ECF No. 48.) Thus, I have not considered Exhibit 90 in my Decision in this case.

Petitioners filed another expert report from Dr. Ratajczak on January 6, 2015 (Ex. 216).

[14] Petitioners erroneously filed Ex. 103 as a "medical record" on May 12, 2014 (ECF No. 63); however, Ex. 103 is the *curriculum vitae* of Helen Ratajczak, Ph.D. (*See* Ex. 103; ECF No. 63).

body and leading to the deleterious effects being described." (ECF No. 68, p. 2, ¶ 4.) In essence, Petitioners seemed to assert that all of W.R.'s injuries are generally caused by the effects of *aluminum* within vaccines, but that there are *multiple theories* from their experts that explain *how* the aluminum within vaccines could have caused W.R.'s specific injuries. (ECF No. 68, pp. 5-7, ¶¶ 16-20; *see also id.*, pp. 2-4, ¶¶ 4-12.)

Petitioners submitted additional medical literature on May 26, 2014. (Exs. 127-134; ECF No. 69.) This case was reassigned to my docket on June 9, 2014. (ECF No. 70.) Over the next year, both parties requested, and were granted, numerous requests for extensions of time to file additional expert reports, and to further supplement the record. (*See* ECF Nos. 72-75, 78-79, 81, 88, 97-98, 100-101.) During that period, Petitioners submitted the expert reports of Richard Deth, Ph.D., and Suzanne Goh, M.D. on January 2, 2015 (Exs. 149-150; ECF No. 84), and filed their respective *curricula vitae* on January 13, 2015 (Exs. 224-225[15]; ECF No. 96). Petitioners also submitted additional medical records and numerous medical literature throughout that period. (*See* Exs. 135-148, 151-223, 226-235; ECF Nos. 82-83, 85-87, 89-95, 99, 102-03, 107.)[16] During that time, Respondent submitted the expert reports and *curricula vitae* of Max Wiznitzer, M.D., and Edward Cetaruk, M.D. (Exs. A-D; ECF No. 76.) The corresponding medical literature cited in those two expert reports was submitted on December 17, 2014. (Ex. A, Tabs 1-9 and Ex. C, Tabs 1-9; ECF No. 80.)

On May 21, 2015, Petitioners filed a status report notifying the court that their experts would not be submitting supplemental expert reports, and that they were ready for this case to be scheduled for a hearing. (ECF No. 104.) Thereafter, Respondent requested, and was granted, several extensions of time to review Petitioners' numerous filings and to retain an additional expert. (ECF Nos. 105-06, 109-110.)

On September 28, 2015, Petitioners filed the expert report and *curriculum vitae* of Judy Mikovits, Ph.D. (Exs. 236-38), and additional medical literature (Exs. 239-240). (ECF Nos. 114-115.) Also on that date, Respondent filed the expert report and *curricula vitae* of Bruce Cohen, M.D. (Exs. E-F), and Jeffrey Johnson, Ph.D. (Exs. G-H), additionally filing the corresponding medical literature cited in those two expert reports (Ex. E, Tabs 1-11 and Ex. G, Tabs 1-15). (ECF No. 113.)

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[15] Exhibits 224 and 225 are mislabeled on the electronic docket as "MEDICAL RECORDS." (*See* ECF No. 96.)

[16] I note that Petitioners mislabeled numerous filings during that time period. The mislabeling errors are as follows: (1) Ex. 215 reflects a letter from a treating doctor, Dr. Civitello, mislabeled as "medical literature" (Ex. 215; ECF No. 93); (2) Ex. 216 reflects the signed expert report of Dr. Ratajczak, mislabeled as "medical literature" (Ex. 216; ECF No. 93); (3) Exs. 224 and 225 are the *curricula vitae* of Drs. Deth and Goh, respectively, mislabeled as "medical records" (Exs. 224-25; ECF No. 96); (4) Ex. 227 reflects a letter from a treating doctor, Dr. Dalton, mislabeled as "medical literature" (Ex. 227; ECF No. 99); and (5) Ex. 234 reflects medical literature, mislabeled as "medical records" (Ex. 234; ECF No. 103).

I granted Petitioners' request for an enlargement of time to file an additional expert report on September 29, 2015. (ECF No. 117.) After holding a telephonic status conference on October 7, 2015, I issued a scheduling and prehearing order on October 8, 2015, providing a schedule for prehearing submissions and outlining the logistical arrangements for a four-day evidentiary hearing. (ECF Nos. 118-19.)[17] At that time, hearing dates were scheduled, for November 30 thru December 3, 2015, and for February 23 and 24, 2016. (*Id.*)

Petitioners filed additional medical literature on October 16, 2015 (Ex. 241; ECF No. 120), followed by a revised expert report from Dr. Deth on October 23, 2015 (Ex. 242; ECF No. 121), and the expert report and *curriculum vitae* of Lawrence Palevsky, M.D. on October 26, 2015 (Exs. 243-44; ECF No. 122). Over the next month, Petitioners submitted additional medical records (Exs. 245-249, 268; ECF Nos. 123, 130) and medical literature (Exs. 250-267; ECF Nos. 124, 126-27), in addition to the supplemental affidavit of Heather Rogero (Ex. 276; ECF 135).[18] During that time period, Petitioners also submitted a list from each expert of the top five medical articles deemed to be the most important to support their expert theory.[19] (ECF No. 125.) Later, those corresponding medical articles were re-submitted, with highlighting of the important sections from each of those articles. (Exs. 269-75, 277-98; ECF Nos. 133, 137-39.) [20]

On November 9, 2015, both parties submitted their respective pre-hearing submissions. (ECF Nos. 129, 131.) On November 25, 2015, an emergency telephonic status conference was held where Petitioners moved for the hearing scheduled for November 30 through December 3, 2015, to be suspended due to a sudden illness in the family of Petitioners' counsel. (ECF No. 140.) I granted that motion. (*Id.*)

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17 I note that due to the vast volumes of medical literature filed in this case, I added a footnote in my prehearing order, suggesting ways to effectively facilitate the use of the medical literature filed in this case. (*See* ECF No. 119.) Specifically, I noted the following:

> Any party wishing to rely upon a medical article is urged to file simultaneously a short explanation of the proposition that the article is intended to support. The relevant portion or portions of the article may be highlighted, boxed, circled or similarly marked. This explanation may be encompassed in the prehearing memorandum, or may appear in a separate document.

(ECF No. 119, p. 2, fn. 2.)

18 Mrs. Rogero's affidavit was improperly filed as "medical records" on the docket. (ECF No. 135.)

19 Petitioners filed that list pursuant to my Scheduling Order of September 2, 2015, urging the parties to file such a list of the most important medical articles. (ECF No. 112.)

20 In filing Exs. 269-275, Petitioners mislabeled those exhibits as "medical records," instead of properly filing them as "medical literature." (Exs. 269-275; ECF No. 133.)

On December 21, 2015, Respondent submitted an expert report of Andrew MacGinnitie, M.D. (Ex. I), the corresponding medical literature from his expert report (Ex. I, Tabs 1-10), and his *curriculum vitae* (Ex. J). (ECF No. 144.)

A telephonic status conference was held on January 15, 2016, to reschedule the hearing of this case. Based on the parties' discussion, I scheduled seven hearing dates from February 25 to March 17, 2016, where both parties' experts in this case, in addition to Heather Rogero, would testify. (ECF No. 146.) Petitioners filed additional medical literature on February 11, 2016 (Exs. 299-303; ECF No. 147), submitting additional medical records on February 15, 2016 (Exs. 304-305; ECF No. 149). [21] On February 23, 2016, Petitioners submitted additional medical literature cited within Dr. Palevsky's report, reflecting relevant portions of those medical articles highlighted. (Exs. 306-320; ECF Nos. 150-51.) [22]

D. Evidentiary hearing and posthearing briefing

A six-day evidentiary hearing was held in Washington, D.C., from February 25 thru March 1, 2016; and on March 14 and 15, 2016. (*See* minute entry of proceedings dated May 13, 2016.) Overall, expert testimony was heard from 11 experts, and one fact witness, Mrs. Rogero. The following seven experts testified on behalf of the Petitioners: (1) Dr. Mary Megson; (2) Dr. Christopher Shaw; (3) Dr. Judy Mikovits; (4) Dr. Richard Deth; (5) Dr. Lawrence Palevsky; (6) Dr. Helen Ratajczak; and (7) Dr. Christopher Exley. The following four experts testified on behalf of Respondent: (1) Dr. Andrew MacGinnitie; (2) Dr. Jeffrey Johnson; (3) Dr. Edward Cetaruk; and (4) Dr. Max Wiznitzer. Over the course of the evidentiary hearing, both parties introduced several trial exhibits, later filing those exhibits into the record. Petitioners introduced

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[21] I note that, in order to give both parties a fair opportunity to fully evaluate the evidence in this case, I set the deadline for filing medical literature for November 23, 2015. (*See* Orders dated Oct. 8, 2015 and Nov. 19, 2015; ECF Nos. 119, 136.) However, my order of October 8, 2015, did *not* apply to the re-filing of *already submitted* medical literature, allowing for already-filed medical literature to be re-submitted with highlighting of the most relevant portions of those articles. (ECF No. 136.)

Disregarding my order of October 8, 2015, however, Petitioners continued to file vast volumes of *new* medical literature after November 23, 2015, even up to the verge of the first day of the rescheduled evidentiary hearing. (*See* Exs. 299-303, 306-320; ECF Nos. 147, 150-151.) Thus, in my order dated February 12, 2016, I once again reiterated my previous orders that no *new* medical article filings would be allowed prior to the hearing. (*See* Order, Feb. 12, 2016; ECF No. 148.)

[22] I note that despite my order dated February 12, 2016, Petitioners filed Exs. 306-20, on February 23, 2016, representing that those exhibits were references cited within Dr. Palevsky's expert report, and that they were filing those articles to rectify that oversight. (ECF Nos. 150-51.)

seven trial exhibits into the record (Exs. 321-27; ECF Nos. 152, 154, and 163),[23] while Respondent introduced five trial exhibits into the record (Resp. Trial Exs. 1-5; ECF No. 153).

Petitioners filed their post-hearing brief ("Pet. PHB") on August 19, 2016 (ECF No. 174), and Respondent filed their post-hearing brief ("Resp. PHB") on November 21, 2016 (ECF No. 177). After several extensions of time, Petitioners filed their reply brief on March 6, 2017. (ECF No. 183.)[24] Thus, this matter is now ripe for a decision.

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[23] I note that two of the trial exhibits introduced by Petitioners into the record were, in fact, *new medical literature* offered into the record of this case. (*See* Ex. 323 ("Petitioners' Trial Ex. C") and Ex. 327 ("Petitioners' Trial Ex. G"); ECF No. 154.) I once again point out that filing those two exhibits was *not* in compliance with *three* of my Orders -- *i.e.*, Orders of Oct. 8, 2015, Nov. 19, 2015, and Feb. 12, 2016 -- orders that explicitly warned both parties that the deadline for filing *new* medical literature was on November 23, 2015. (*See* ECF Nos. 119, 136, and 148; *see also* fns. 24 and 25 immediately above.)

I additionally note that Ex. 324 (also known as Petitioners' Trial Ex. D), comprised of a slide deck presentation used during the direct testimony of Dr. Deth, and was in fact *different* from the slide deck emailed to Respondent's counsel by Petitioners' counsel prior to the evidentiary hearing. (*See* Tr. 363-364.) Although I acknowledged Respondent's counsel's concerns about the lack of fundamental fairness to Respondent's experts (effectively giving them inadequate time to properly prepare to address Dr. Deth's direct testimony based on those slides), I nonetheless allowed for Ex. 324 to be offered into evidence, after admonishing Petitioners' counsel for his actions. (*See* Tr. 362-366.)

[24] Petitioners attached a lengthy document to their reply brief, labeling that exhibit as "Appendix A." (ECF No. 183-1.) Petitioners' sur-reply brief represented that Appendix A was a document compiled by the Petitioners, listing W.R.'s medical records chronologically, with explanations and highlighting of medical records that the Petitioners believed were purposely omitted from discussion in Respondent's expert reports and in Respondent's post-hearing brief. (ECF No. 183, p. 6.) As explained in detail in Section XVII below, I find those allegations, among others, made by the Petitioners and their counsel, accusing Respondent's counsel and Respondent's experts of various misconduct, to be baseless.

Similarly, as also explained in Section XVII, upon my close examination of the record of this case and in my careful study of Appendix A, I find Appendix A to be *wholly unreliable*, serving to actually *confound* the record of this case. In this regard, I point out that one major argument advanced by Petitioners in their sur-reply brief is that Respondent's experts omitted evidence of W.R.'s alleged regressions after his vaccinations, especially after his DTaP vaccination of May 4, 2010. I point out, however, that Appendix A contains numerous statements that appear to be *interpretations* of W.R.'s contemporaneous medical records by the *Petitioners themselves* -- interpretations of W.R. medical records in which Petitioners seemingly *self-diagnose* W.R.'s apparent regressions after his vaccinations. Further, I note that *none* of W.R.'s treating medical care providers, *close in time to his vaccinations*, actually attributed *any* of W.R.'s symptoms to his vaccinations.

IV

FACTS

A. Medical history appearing in the medical records

W.R. was born on September 10, 2008, in Tulsa, Oklahoma. (Ex. 38, pp. 7-9, 12.) He was seen for newborn checkups by Carl Pfanstiel, M.D., on September 17 and 30, 2008. (Ex. 7, pp. 8-9.) Those visits were unremarkable, and he was overall assessed as being healthy. (*Id.*)

1. W.R.'s first set of vaccinations, and following care

W.R. was seen by Christopher Dalton, D.O., on November 19, 2008, presenting with "bad cradle cap," congestion, cough, sneezing, and "green nasal drainage." (Ex. 35, p. 4.) Developmental testing at that time revealed that he passed a majority of his developmental milestones, but failed the milestone of "turns head to sound." (*Id.*) W.R. was administered the Pediarix (a combination vaccination comprised of the diphtheria/tetanus/pertussis (DTaP), hepatitis B, and inactivated polio vaccines), Hib (Haemophilus influenzae type B), and pneumococcal vaccination. (*Id.*, p. 5.)[25]

On December 3, 2008, W.R. was seen by Dr. Dalton for eye drainage and rash. (Ex. 35, pp. 6-7.) At that time, his parents reported that W.R. had a white discharge and redness around his arms for one week, and that his cradle cap was "significantly better." (*Id.*, p. 6.) Upon examination, Dr. Dalton assessed that W.R. had seborrhea (discharge) around his eyelids, infantile eczema on his trunk and extremities, but that his cradle cap from his prior visit was "significantly improved." (*Id.*, pp. 6-7.) On January 3, 2009, W.R. was seen at Saint Francis Hospital for cough and congestion -- symptoms that his parents reported were ongoing for the past month. (Ex. 35, p. 8; Ex. 24, p. 8.)

2. W.R.'s second set of vaccinations, and following care

W.R. had his four-month well-visit on January 19, 2009. (Ex. 35, pp. 11-12.) At that time, his mother reported W.R. having problems of spitting up after eating and while lying down for a diaper change. (*Id.*, p. 11.) W.R. passed most of his four-month developmental milestones,

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[25] On November 25, 2008, Mrs. Rogero, W.R.'s mother, received an influenza vaccination ("Tri Flu Fluzone"). (Ex. 83, p. 1.) As discussed in Section V(A)(7)(b) below, at least one of Petitioners' experts opined that W.R. was also negatively affected by Mrs. Rogero's flu vaccination of November 25, 2008, claiming that through breastfeeding W.R. ingested certain particles from that flu vaccination that they believed were harmful, but I found no merit in that allegation.

but failed the milestone of "rolling." (*Id.*) He received Pediarix and pneumococcal vaccinations at that time.[26] (*Id.*)

On February 13, 2009, W.R. had a follow-up visit to evaluate his rash. (Ex. 35, pp. 52-53.) That record reflects that eczema was present at the back of his knees and at the base of his neck, but that his cradle cap was "much improved." (*Id.*, p. 52.) Mrs. Rogero reported that W.R. was continuing to spit up and that he had ongoing problems gaining weight. (*Id.*) Overall, W.R. was assessed as still being underweight, having a failure to thrive, and having feeding difficulties. (*Id.*, p. 53.)

On March 2, 2009, W.R. was seen by Dr. Dalton for complaints of a cough that was reported to be ongoing for the previous five days, and for congestion. (Ex. 35, pp. 13-14.) Dr. Dalton suspected that W.R. had a respiratory syncytial virus (RSV), and arranged for admission at St. Francis Children's Hospital due to W.R.'s need for suctioning. (*Id.*, p. 14.) Upon admission at St. Francis Children's Hospital, W.R. was diagnosed as having RSV bronchiolitis. (Ex. 35, pp. 15, 35-36; Ex. 24, pp. 57-64, 66.)

W.R. was seen in urgent care on March 7, 2009, presenting with a cough and a fever of 101.3 degrees Fahrenheit. (Ex. 21, p. 5.) W.R.'s physician diagnosed him with having right otitis media (ear infection) and an unspecified fever, and prescribed an antibiotic ("omnicef"). (*Id.*)

On March 11, 2009, W.R. was seen by Dr. Dalton as a follow-up for his RSV diagnosis of March 2, 2009. (Ex. 35, p. 19.) At that time, Mrs. Rogero reported that W.R. "was not rolling over," and that he still had a cough. (*Id.*) Under the "[a]ssessment/[p]lan" section of that record, Dr. Dalton recorded that W.R.'s "acute bronchiolitis due to RSV" was "resolved," and assessed W.R. to be underweight. (*Id.*, p. 18.)[27] Dr. Dalton referred W.R. to SoonerStart, an early intervention developmental therapy program. (*Id.*, p. 18.)

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[26] W.R.'s immunization records contain several ambiguities regarding W.R.'s second set of vaccinations. Records from W.R.'s well-visit of January 19, 2009, reflect a notation of "completed" for the Pediarix and pneumococcal vaccinations, while reflecting a notation of "cancelled" for the "Hib" and "Varicella" vaccinations (likely meaning that W.R. was not administered the Hib and Varicella vaccinations at that time). (*See* Ex. 35, p. 12.) That is, it appears from that record that W.R. received only two vaccinations on that date -- the Pediarix (a combination vaccine of the DTaP, hepatitis B, and inactivated polio vaccines) and the pneumococcal vaccination.

[27] I note that W.R.'s records from his visit of March 11, 2009, are filed in reverse chronological order. Thus, Ex. 35, p. 19 is the first page of that record, followed by Ex. 35, p. 18. (*See* Ex. 35, pp. 18-19.)

W.R. was seen by SoonerStart on April 10, 2009. (Ex. 18, p. 29 of 48.)[28] That record reflects that W.R.'s parents reported "knowing he is delayed developmentally," but that they had "no specific concerns" at that time. (*Id.*) Moreover, W.R.'s developmental therapist recorded, among other things, that W.R.'s parents were advised to:

> [L]imit amount of time they hold him in standing until he is rolling and sitting independently and trying to crawl.

(Ex. 18, p. 29 of 48.)

On April 13, 2009, W.R. was seen by Dr. Dalton for complaints of green nasal drainage from his nose and eyes for one week, a cough for the past four days, wheezing for the past three days, and a high temperature that started the previous day. (Ex. 35, p. 20.) He was diagnosed with otitis media (ear infection), and was prescribed an antibiotic. (*Id.*, p. 21.) W.R. continued to be assessed as being "underweight." (*Id.*)

W.R. was seen at urgent care on April 25, 2009, with a chief complaint of "sporadic rashes all over." (Ex. 21, p. 3.) W.R. was diagnosed with "unspecified urticarial" (hives), and prescribed an antibiotic. (*Id.*, p. 4.)

3. W.R.'s third set of vaccinations, and following care

On April 27, 2009, W.R. was seen by Dr. Dalton to be re-evaluated for his hives and congestion. (Ex. 35, pp. 23-24.) At that time, Mrs. Rogero reported, among other things, that W.R. was "beginning to prop up," and that he had "started to roll over quite a bit." (*Id.*, p. 23.) Overall, W.R. was assessed as having atopic dermatitis, due to "drugs-medicines taken internally." (*Id.*, p. 24.) In addition, W.R. was administered the Pediarix and pneumococcal vaccinations at that time.[29] (*Id.*)

a. Routine care visits and specialist evaluations

W.R. was seen for his nine-month well-visit on June 16, 2009. (Ex. 35, pp. 26-27.) At that time, W.R. failed most of his developmental milestones. (*Id.*, p. 26.) W.R. was assessed as being underweight, having short stature, and as being "off on his development and delayed." (*Id.*, p. 27.) W.R. was referred to have a genetic evaluation for his developmental delay and short stature. (*Id.*, pp. 27-28.) [MOTOR ONLY SPEECH NOT DELAYED NOR SOCIAL]

On July 20, 2009, W.R. was examined by geneticist Michael Kayser, D.O., for developmental delays and failure to thrive. (Ex. 17, pp. 4-5.) At that time, Mrs. Rogero reported W.R.'s recent developmental history, stating, *inter alia*, that "[d]evelopmentally, [W.R.] sits with

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[28] The pagination in this record is reflected in the bottom left-hand corner of the page. (*See* Ex. 18 generally.)

[29] In her affidavit, Mrs. Rogero alleged that W.R. also received a Hib vaccination at his visit of April 27, 2009. (Ex. 276, p. 8, ¶ 37.)

support." (*Id.*, p. 4.) Overall, Dr. Kayser assessed W.R. as having developmental delays and failure to thrive, and discussed possible genetic abnormalities that could explain W.R.'s developmental condition, ordering laboratory testing to rule out those possibilities. (*Id.*, p. 5.)

On July 31, 2009, W.R. saw an allergist to determine whether W.R.'s lack of growth could be due to food allergies. (Ex. 19, p. 1.) That record documents a medical history of W.R., as reported by Mrs. Rogero, indicating that W.R. had a history of "severe reflux," and that he had experienced eczema "since 2-3 weeks old." (*Id.*) The allergist recommended certain skin testing. (*Id.*, p. 2.)

b. Developmental therapy sessions

From May to mid-July of 2009, W.R. had several developmental therapy sessions with SoonerStart Early Intervention Program. (Ex. 18, pp. 1-6 and pp. 18-28 of 48.)[30] On his evaluation of May 5, 2009, W.R. had a "sluggish pupillary response" on vision testing (Ex. 18, p. 1 of 48), and Mrs. Rogero reported that her biggest concerns regarding W.R.'s development were his motor skills and certain of his speech skills (*id.*, p. 27 of 48). The therapy records reveal his therapists' ongoing focus on developing certain of his motor skills. (*See generally* Ex. 18.)

4. W.R.'s fourth vaccination visit, and following care

W.R. next received a Hib vaccination on August 1, 2009. (Ex. 1, p. 3.)

a. Routine care visits and specialist evaluations

On August 20, 2009, W.R. was seen by the allergy clinic to review the results of his allergy testing conducted on July 20, 2009. (Ex. 19, pp. 7-8.) At that visit, Mrs. Rogero, among other things, reported that W.R.'s eczema was "under control" (*id.*, p. 8), and he was assessed as having an allergy to eggs and having atopic dermatitis (*id.*, p. 7).

b. Developmental therapy sessions

W.R. had several developmental therapy sessions with SoonerStart in August of 2009. (Ex. 18, pp. 18-20 of 48.) Collectively, those records reveal that W.R. made some progress in ~~speech~~ and motor development. (*Id.*) Those records also contain a notation dated September 1, 2009, documenting that Mrs. Rogero cancelled further developmental services due to her belief that W.R. was doing well. (Ex. 18, p. 45 of 48.) [SPEECH WAS NOT DELAYED, RECORD STATES SAYING BA, KA, MA...]

5. W.R.'s fifth set of vaccinations, and following care

W.R. was seen by Dr. Dalton for his one-year well visit on September 24, 2009. (Ex. 35, pp. 29-31.) At that time, W.R. failed a majority of his developmental milestones. Upon examination, W.R.'s eczema was "much improved," but was observed to have a "mild

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[30] For clarity, I note that several of the SoonerStart records were filed in reverse chronological order. (*See* Ex. 18, pp. 21-28 reflecting SoonerStart visits from May 18 to July 14.)

strabismus" (commonly referred to as being "cross-eyed"). (*Id.*, p. 30.) He was assessed as being "underweight" and having "mechanical strabismus," and Dr. Dalton placed an order for W.R. to receive his hepatitis A and varicella vaccinations at that time. (Ex. 35, pp. 29-31.) [SAYING MAMA AND DADA ON MD NOTES, NOT WALKING YET, NO SOCIAL DELAY]

a. Vaccinations administered on September 24, 2009

W.R.'s medical records contain discrepancies regarding the precise vaccinations that were given on September 24, 2009. For instance, W.R.'s record of his well-visit with Dr. Dalton on September 24, 2009, reflects that the "[h]ep A" and "[v]aricella" vaccinations were "ordered" on that date. (Ex. 35, p. 31.) In contrast, however, another medical record labelled as "PATIENT IMMUNIZATION RECORD" from the "Warren Clinic" reflects that W.R. was in fact administered the hepatitis A and Hib vaccinations on September 24, 2009. (Ex. 35, p. 34.)

b. Routine care visits and specialist evaluations

W.R. was seen on November 9, 2009, by an ophthalmologist, who, among other things, diagnosed him as having neurodevelopmental delay. (Ex. 12, p. 1.) On December 17, 2009, W.R. had a follow-up appointment with his geneticist, Dr. Kayser. (Ex. 17, p. 2.) That record reflects that W.R.'s chromosomal testing results were normal. (Ex. 17, p. 2; *see also* Ex. 24, p. 49.) Dr. Kayser recorded a medical history of W.R., stating that W.R. "has been tested developmentally and does fall between four to five months behind on most milestones." (Ex. 17, p. 2.) Among other things, Dr. Kayser recommended that early intervention services should be continued at that time to "maximize [W.R.]'s development." (*Id.*)

On December 18, 2009, W.R. had his fifteen-month well-visit with Dr. Dalton. (Ex. 35, pp. 32-33.) The record of that visit reflects that W.R. was "essentially behind with fine motor skills and language development" (*id.*, p. 32), and a physical evaluation revealed that he had "eczemic and allergic dermatitis" on his face and legs (*id.*, p. 33). Accounting for the family's planned move to the Washington D.C. area, Dr. Dalton recommended that W.R. needed aggressive speech and physical therapy moving forward, and that W.R. should consult with a developmental pediatrician upon moving. (*Id.*, p. 33.)

c. Developmental delay testing and therapy sessions

At approximately 15 months of age, W.R. had another developmental assessment on December 4, 2009. (Ex. 8, pp. 2-3.) At that time, he failed a majority of his developmental milestones. (*Id.*)

On December 23, 2009, W.R. had a final evaluation with SoonerStart prior to the family's upcoming move to the Washington D.C. area. (Ex. 18, p. 16.) Among other things, W.R.'s developmental therapist recorded Mrs. Rogero's report that W.R. had "many perceptual motor delays" at that time. (*Id.*)

W.R.'s medical records reflect that upon moving to the Washington area, he received developmental assessments and therapy sessions through several providers. (Ex. 34.) At that time, W.R. was assessed as being behind in ~~several~~ key developmental areas (*id.*, pp. 2-6), and it

was determined that he would benefit from early intervention services to support his motor, speech, and language development during daily routines (*id.*, p. 5).[31] From February through September of 2010, W.R. continued receiving developmental, occupational, and speech therapy sessions in Arlington, Virginia. (Ex. 34, pp. 8-9, 12-14, 20, 44-69.) [WALKING AND SPEECH SESSIONS ONLY, RECORD STATES SAYING BOOK, WAVING, POINTING, EYE CONTACT A STRENGTH, SEE JAN-APRIL ACTUAL RECORDS]

6. W.R.'s sixth vaccination visit, and following care from May through Sept. of 2010

[WAS 19-MONTH DTAP]

W.R. had his 20-month well-visit with Barbara Stevens, M.D., on May 4, 2010. (Ex. 5, p. 5.) W.R. was assessed as having developmental delays at that time, and was administered the DTaP vaccination. (*Id.*) **[§300aa-11(c)(1)(A)-(B)(i)(1) FOUND]**

a. Routine care visits

W.R. had a follow-up appointment with Dr. Stevens on May 7, 2010, with no report of regression or any ~~negative symptoms~~. (Ex. 5, p. 6.) On June 28 and 30, 2010, W.R. was seen by Dr. Stevens for an evaluation for rhinorrhea and constipation. (*Id.*, pp. 3-4.) Among other things, those records from Dr. Stevens reflect a description of W.R. as a 21-month-old boy with failure- to-thrive and autism. (*Id.*) [MD REPORTS SKIN ERRUPTIONS (AGAIN) AFTER DTAP, AND WITHELD 2 VACCINES OF HER CONCERN OF MITOCHONDRIAL D.O.]

*****[ALL RELEVANT MAY-JULY ENCEPHALOAPTHY RECORDS ARE ABSENT THE DECISION] [MAY MEDICAL RECORDS DOCUMENTS CONCERN, AND LOSS OF CLAPPING]

W.R. switched pediatricians in late July of 2010, starting care with pediatricians from Capital Area Pediatrics. (*See* Ex. 33 generally.) Specifically, W.R. had a consultation with a pediatrician from that practice group on July 20, 2010, with a complaint of "autism." (*Id.*, p. 3.)[32] That record reflects a medical history of W.R. given by Mrs. Rogero, reporting, among other things, that W.R. had eczema issues ~~since he was one month of age~~, but that they had improved since Mrs. Rogero eliminated eggs from W.R.'s diet. (*Id.*) Additionally, she reported that W.R. had food allergies as revealed through "patch testing," was "developmentally behind in all areas," was late to walk (reporting that he started to walk in May 2010), and that he had "no speech." (*Id.*)[33] W.R.'s physician documented a plan to follow up with certain of W.R.'s medical care providers, recommending that Mrs. Rogero start W.R. on physical therapy ("PT"), occupational therapy ("OT"), and speech therapy ("ST"). (*Id.*, p. 2.)

[JUNE RECORD ON EXAM DOCUMENTS NO MORE EYE CONTACT, AND UNAWARE OF ENVIRONEMENT, GUTTURAL SOUNDS NO, AND NO SPEECH, EXAMINED AND LOST 12 MONTHS OF SKILLS BY JULY, FOUND DISORIENTAL ALL SPHERES AND DISABLED BY JULY 8 AFTER DTAP]

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[31]Specifically, W.R. was in the 9-12 months developmental age range for his gross motor and fine motor skills (Ex. 34, p. 3); in the 12-16 months developmental age range for his adaptive skills (*id.*); in the 5-6 months developmental age range for his expressive language skills (*id.*, p. 4); at the 6-months age level for his receptive language skills (*id.*); at the 12-months age level for cognitive skills (*id.*); and his social and emotional skills were estimated to be between 12-18 months of age (*id.*). [at 16.5 month exam]

[32]For clarity, I note that Ex. 33, p. 3 reflects the first page of W.R.'s evaluation of July 20, 2010, and Ex. 33, p. 2 is the second page of that evaluation. (Ex. 33, p. 3.) [33]That record also reflects Mrs. Rogero reporting, among other things, that she was concerned that W.R. had "mercury poisoning," and that she had "done much reading on [the] internet" about autism, speculating about several possibilities as to the causes of W.R.'s then- present condition. (Ex. 33, p. 3.)

W.R.'s medical records from Capital Area Pediatrics reflect a notation made on July 21, 2010, by one of W.R.'s pediatricians from that practice, reporting entries of that pediatrician's follow-up calls with W.R.'s various treatment providers. (Ex. 33, p. 2.) That record reflects that W.R.'s pediatrician from Capital Area Pediatrics spoke with another one of W.R.'s treatment providers, Polly Panitz, M.D., and documented Dr. Panitz's assessment of W.R. at that time. That record reflects the following:

[FOUND AT RISK FOR AUTISM, NO DIAGNOSES, AFTER ENCEPHALAOPTHY ONSET]
She [Dr. Panitz] does not feel that food allergies or the mercury? are the cause of autism [and] spoke [with] mom about this. She will call her again [and] reiterate that testing for mercury will not be helpful [and change] in diet will not cure autism but may help [W.R.] be more comfortable.
[MERCURY CONCERN WAS FROM A FILLING THAT BROKE WHILE STILL NURSING IN RECORD]

(Ex. 33, p. 2.) Moreover, that pediatrician from Capital Area Pediatrics also spoke with another one of W.R.'s treatment care providers, Oral Alpan, M.D., recording the following notes from that conversation:

> I spoke [with] Dr. Alpan [and] he does not feel this is IgE mediated allergy. If this is an eosinophilic enteritis some food elimination may be helpful for comfort but not curative of the other developmental issues. He did patch testing which correlates [with] eosinophilic enteritis [and is] not IgE mediated.

(Ex. 33, p. 2.)

b. Emergency department visits

W.R. had two emergency department visits in July and September of 2010. (Ex. 31, pp. 13-29.) On July 22, 2010, W.R. was admitted to the emergency department for complaints of erythematous plaques around his mouth, swelling of the lip and tongue, and wheezing. (Ex. 31, pp. 21-29.) At that time, he was assessed as having an allergic reaction. (*Id.*) W.R. was seen again by the emergency department on September 18, 2010, for complaints of cough and congestion, and was assessed with having an acute upper respiratory infection, not otherwise specified ("Acute URI NOS"). (*Id.*, p. 13.)

c. Specialist evaluations

W.R. was evaluated by several specialists from June to September 2010. I discuss those visits below.

i. Developmental pediatrician **[ALL RELEVANT MD FINDINGS ARE ABSENT HERE AND BELOW INCLUDES HISTORY MIXED WITH ACTUAL EXAM PORTION OF THE RECORD AND IS MISCONSTRUED FROM ACTUAL EXAM PORTION]**

On June 8 and 15, 2010, W.R. was evaluated by a developmental pediatrician, Polly Panitz, M.D. (Ex. 6, pp. 3-6.) During those visits, Dr. Panitz took W.R.'s medical history, as reported by his parents, stating that W.R. "is able to babble, but does not use language in any meaningful way," "makes eye contact, but doesn't always respond to being called or verbal requests," and that he "does not point or use other gestures." (*Id.*, p. 3) At that time, W.R. was administered the "STAT" test (standardized test of autism for children two years of age), revealing that W.R. was "well above the threshold for 'at risk' for autism." (*Id.*, p. 5.) On

language and cognitive testing, W.R. was assessed as having "severely delayed" language skills, but was assessed as having normal cognitive skills. (*Id.*) Overall, Dr. Panitz assessed W.R. as having "receptive and expressive language skills" that are "significantly delayed," and as having significant delays within his "non-verbal communicative intents." (*Id.*) Dr. Panitz overall assessed W.R. as follows:

> [W.R.] engages in repetative (*sic*) and restricted behaviors and meets the DSM [Diagnostic and Statistical Manual] criteria for Autism. Due to his young age, we will defer the assignment of this diagnostic label until after his 2nd birthday, even though the literature indicates that the presence of these significant findings is likely to be consistent.

(Ex. 6, p. 5.) Additionally, Dr. Panitz recorded that she was concerned about W.R.'s failure to thrive, and that his weight was "most significantly impaired and inadequate for his height," recommending that W.R. be evaluated by several specialists. (*Id.*, pp. 5-6.)

ii. Consultations with allergists

From July thru September of 2010, W.R. was seen on several occasions by an allergist, Dr. Oral Alpan, and underwent numerous testing for potential allergies. (*See* Ex. 25, pp. 10-17; Ex. 44, pp. 3-6, 7-8.) Collectively, those records reveal descriptions of W.R. during that time, as reported by his parents, reflecting that he had ongoing weight problems, frequent diarrhea, eczema still present, and a rash. (Ex. 25, p. 11; *see also* Ex. 44, p. 6.) Additionally, W.R.'s evaluations by Dr. Alpan during that time period reflect that W.R. underwent "patch testing" revealing "multiple food allergies" (Ex. 25, pp. 10, 12; Ex. 44, pp. 4-5), and was assessed with the following: "dermatitis/atopic/eczema," "allergic gastritis," and "FTT" (failure to thrive) (Ex. 44, p. 5).

iii. Neurological consultations

On August 18, 2010, W.R. was evaluated by a neurologist, Stella Legarda, M.D. (Ex. 28, pp. 13-15.) That record reflects that Mrs. Rogero requested that evaluation with Dr. Legarda, and Dr. Legarda's records from that consultation reflect the following:

> Mom describes [W.R.] to occasionally seem to have unresponsive episodes and would like him to be evaluated for possible seizures, something she has read may be present in autism.

(Ex. 28, p. 13.) Overall, Dr. Legarda assessed W.R. as having an "autistic disorder current or active state," and with having "other convulsions." (*Id.*, p. 14.) In that medical record, Dr. Legarda further elaborated upon her assessment of "other convulsions," noting the following:

> Routine EEG [electroencephalogram] is ordered. These episodes do not seem significant, nevertheless it is helpful to obtain a baseline study evaluation in children with autism.

(Ex. 28, p. 14.) A 23-hour EEG study conducted on October 25, 2010, reflects that his results were "within normal limits" and that "no epileptiform [seizure] activity" was seen on that test. (Ex. 9, p. 144.)

On September 29, 2010, W.R. was seen by another neurologist, Lucy Civitello, M.D., with his chief complaint listed as "test; rule out other things." (Ex. 9, p. 154.) That record reflects an admitting diagnosis of "[e]ncephalopathy NOS [not otherwise specified]." (*Id.*, p. 153). Under the patient history section of that record ("HPI"), Dr. Civitello recorded W.R.'s medical history as reported by Mrs. Rogero. (*See id.*, p. 154; *see also id.*, pp. 155, 157.) In this regard, Dr. Civitello recorded statements made by Mrs. Rogero, reporting, among other things, that W.R. had a diagnosis of autism, that he was possibly vaccine injured due to aluminum-based vaccines given to him at two, four, and six months of age, and that he had "severe eczema." (*Id.*, p. 154.) [RELEVANT MD FINDINGS ABSENT HERE TO ENCPAHLOPATHY]

[DOCUMENTS FOCAL NEUROLOGICAL SIGNS OF CRANIAL NERVE 7 INJURY ON RIGHT SIDE OF FACE, LOW TONE, NO MORE BABBLING, GUTTURAL OF ENCEPHALAOPTHY AND ALSO NOTES A PSYCHIATRIC BOX OF AUTISM] DOCUMENTS VACCINE INJURY OF SKIN ISSUES FROM ALUMINUM VACCINES, REGRESSION AFTER MAY DTAP] DOCUMENTS ENCEPHALOPATHY AND AUTISM AT SAME VISIT

iv. Other specialist evaluations

On July 6, 2010, W.R. had a consultation with a cardiologist who recorded a medical history of W.R. described by his parents, reporting that W.R. had undergone "a number of evaluations for developmental issues," including evaluations for "autism, GI problems and significant failure to thrive." (Ex. 20, p. 1.) Upon examination, the cardiologist assessed that W.R.'s then-present issues were not related to any cardiac conditions. (*Id.*)

W.R. was evaluated on July 28, 2010, by a gastroenterologist, Benjamin Enav, M.D., for a complaint of food allergies. (Ex. 14, pp. 1-2.) The "past medical history" section of that record states the following about W.R.'s developmental delay:

> Presumed autism diagnosed in May 2010, the ~~mother believes is mercury induced,~~ history of RSV, history of [food] allergies, and eczema. [INCORRECT, CONCERNED OF FILLING THAT BROKE WHILE NURSING]

(Ex. 14, p. 1.) Overall, Dr. Enav diagnosed W.R. as having a "failure to thrive," and recommended further testing and follow-up appointments with a dietician. (*Id.*, p. 2.)

d. Developmental therapy sessions and public school evaluations

W.R. had numerous developmental therapy sessions from May through September 2010. Those records collectively reflect his developmental therapists working with W.R. to meet various developmental target goals. (*See* Ex. 34, pp. 10-12, 16-19, 25-36, 39, 41-42, 51-53, 55-59, 61-62.) Moreover, W.R. received numerous special education services through Arlington County Public Schools, and had frequent evaluations to assess his then-present levels of academic and functional performance, relative to his developmental delays. (Ex. 4, pp. 41-44; 61-71; 73-86.) **[POST DTAP SHOWS LOSS OF 12 MONTHS OF SOCIAL/EMOTIONAL SKILLS TO A 6 MONTH OLD COMPARED TO 16.5 MO OLD EXAM]**

During that time period, W.R. also had disability evaluations from state and federal government health departments, assessing the extent of public services to be provided to meet his developmental needs. (*Id.*, pp. 2-13; 19.) Collectively, those records indicate that W.R. was

getting state and local services for his developmental delays that were attributed to his autism spectrum disorder. (Ex. 22, pp. 2, 6, 13, 19.)[34]

[WAS A *MEDICAL* NEEDS NOT BEHAVIOAL AUTISM AND FOUND DISORIENTED ALL SPERES – LEVEL 3 of ENCEPHALAOPTHY]

7. Medical records since October of 2010.

The record of this case contain extensive records of W.R.'s medical treatment, developmental therapies, evaluations, and other documents relating to the period from October of 2010 forward. I have reviewed those records, and taken them into account in my Decision, but I will not describe them in detail here, because they have relatively little relevance to the causation issues that I decide here. Those records demonstrate that, tragically, W.R. has continued to suffer from an autism spectrum disorder, developmental delays, and other medical conditions. [ENCEPHALOPTHY IN MEDICAL RECORDS AND DISTINGUISHED FROM AUTISM]

[DR PANITZ DOCUMENTS INCREASED EYE CONTACT FROM JUNE EXAM – CIRCUMSTANTIAL OF HIS ENCEPHALAOPTHY ONSET MAY-JUNE]

B. Additional factual allegations made by Petitioners

1. Affidavits of Heather Rogero

[MOM WAS STATING FIRST HAND KNOWLEDGE FROM HIS MD'S AND SCIENTISTS]

W.R .'s mother, Heather Rogero, signed affidavits on August 14, 2012 (Ex. 40), and November 5, 2015 (Ex. 276). In both of her affidavits, Mrs. Rogero made numerous statements that veered into ~~medical opinion~~ testimony, offering ~~her own opinions~~ regarding medical and scientific issues that are central to this case.[35] I discuss those statements, in addition to her

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[34] Ex. 22 also reflects the approximate dates of W.R.'s various diagnoses, as reported by Mrs. Rogero to the staff members that evaluated W.R. during his Virginia Disability Assessment of July 8, 2010. (Ex. 22, p. 6.) In this regard, under the "Current Diagnoses" section of that medical record, W.R.'s "failure to thrive" diagnosis reflects an approximate date of onset of "December 2008"; his ~~"[a]utism" diagnosis reflects an approximate date of onset of "June~~ 2010"; [ACTUAL RECORD STATES CONCERN OF AUTISM, AND FOUND "DISORIENTED ALL SHERES, LEVEL 3- LEVEL 5 IS COMATOST, SIGNED BY MD] his "[e]czema" diagnosis reflects an approximate date of onset of "September 2008." (*Id.*)

[35] *See* Ex. 276, p. 5, ¶ 16 (Mrs. Rogero stating that W.R.'s eczema symptoms that temporally occurred after his first set of vaccinations were "an adverse effect" of those vaccinations) [SEE MEDICAL RECORD AND EX 227] ; *Id.*, ¶ 18 (Mrs. Rogero stating that W.R.'s upper respiratory infection of January 3, 2009, was an adverse effect of his first set of vaccinations); Ex. 276, p. 8, ¶ 35 (Mrs. Rogero stating that W.R.'s "sluggish pupillary response," recorded in his treating doctor's evaluation records from April 10, 2009, was a "neurological injury indicator"); *Id.*, p. 12 (Mrs. Rogero presenting a chart listing what she deemed to be "mitochondrial dysfunction biomarkers" from W.R.'s medical records); *Id.*, p. 13, ¶ 54 (Mrs. Rogero discussing certain studies that she deemed reflected a "biologic plausibility" of the type of neurological injuries that W.R. sustained, and stating that W.R.'s "high glutamate" and "microglial activation" were triggered by vaccinations as they were the "only thing not ruled out"); *Id.*, p. 15, ¶ 63 (Mrs. Rogero stating that W.R.'s apparent low "IGF-1" levels were a risk factor for "adverse effects from vaccinations"); *Id.*, p. [QUOTING DR DETHS THEORY OF THIS CASE] 19, ¶ 85 (Mrs. Rogero stating that certain of W.R.'s symptoms "do not fall under the criterion for autism"); *Id.*, pp. 19-20, ¶ 89 (Mrs. Rogero stating that certain symptoms of W.R. are "characteristic of his encephalopathy NOS [not otherwise specified], which progressed in his neurological records to a chronic encephalopathy to a chronic static encephalopathy"); *Id.*, p. 20, ¶ 90 (Mrs. Rogero stating that that she spoke with a certain expert regarding how "it would be impossible for vaccination to cause autism" and that they discussed "how encephalopathy ~~could~~

~~testimony at the evidentiary hearing~~ in Section XVII , below. In this section, however, I simply list *additional factual allegations* made by Mrs. Rogero that have not been discussed previously.[36]

[SEE ACTUAL EVIDENCE THIS IS THE MASTER'S ASSUMPTIONS ON HEARING, IT WAS NOT DISCUSSED WITH NIMH DIRECTOR], EX. 276 at 20 AND HE LEAVES OFF PAGE NUMBER] -

a. W.R.'s alleged symptoms following his fourth set of vaccinations on August 1, 2009

Mrs. Rogero alleged that, soon after his Hib vaccination of August 1, 2009, W.R. would just "flop over when sitting". (Ex. 276, p. 9, ¶ 44.)

b. W.R.'s alleged symptoms following his sixth set of vaccinations[37]

i. W.R.'s alleged condition following his sixth vaccination set

Mrs. Rogero alleged that there were many differences between W.R.'s behavior prior to his May 2010 DTaP vaccination versus after that vaccination. (*E.g.*, Ex. 276, p. 10, ¶¶ 47, 51; *Id.*, p. 19, ¶ 89.) In this regard, she alleged that "something happened after" that vaccination, claiming that after that time, W.R. was "in and out of starring [staring] spells" and that, especially in the summer and fall of 2010, he appeared to "be in his own world." (*Id.*, p. 19, ¶ 89.) Moreover, she alleged that W.R.'s staring spells could not be "confirmed or denied" from his medical records, claiming that testing conducted during that time period did not properly document his staring spells. (*Id.*, p. 11, ¶ 53.) In this regard, she discounted W.R.'s EEG testing results conducted in October of 2010, claiming that, prior to the start of that EEG test, W.R. had a "spacy presentation" that was not recorded due to his EEG testing machine not being "turned on" at that time. (*Id.*, p. 11, ¶ 53.) [ALL FOUND ON MD EXAMS IN THAT TIME PERIOD ABSENT THIS DECSION]

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be caused by vaccination"); *Id.*, ¶ 91 (Mrs. Rogero stating possible theories of causation for W.R.'s injuries); *Id.*, ¶ 92 (Mrs. Rogero stating her views on the purported high dosage of aluminum administered to W.R. from his vaccines).

[36] I note that in both of her affidavits, Mrs. Rogero stated that the record of this case was missing records of one specific appointment that W.R. had with pediatrician Dr. Dalton, occurring between W.R.'s second and third set of vaccinations, for a re-evaluation of a rash. (Ex. 40, p. 4 of 11, ¶ 17; Ex. 276, p. 6, ¶ 24.) That record was subsequently submitted into the record of this case as Ex. 35, pp. 52-53.

[37] In comparing Mrs. Rogero's affidavits with W.R.'s vaccination records in this case, I note that there is a discrepancy regarding the *exact type* of vaccination given to W.R. on May 4, 2010. (*Compare* Ex. 5, p. 2 and Ex. 1, p. 1, with Ex. 40, p. 7 of 11, ¶ 42 and Ex. 276, p. 11, ¶ 53.) In this regard, both of her affidavits state that W.R. received the *Pediarix* vaccination on that date, while W.R.'s vaccination records reflect that he was only administered the DTaP vaccination. (*Id.*) At the evidentiary hearing, Mrs. Rogero stated that W.R. received the *Pediarix vaccine* on May 4, 2010, but referred to that vaccination as the "DTaP" vaccine, referencing one of W.R.'s vaccination records, Ex. 5, as support for her testimony. (Tr. 530-31.) I note, however, that Ex. 5 reflects that W.R. was in fact administered the DTaP vaccination -- and not the Pediarix vaccination -- on May 4, 2010. (*See* Ex. 5.)

Additionally, Mrs. Rogero's affidavits listed selective language from certain of W.R.'s medical records in order to describe W.R.'s condition before and after his DTaP vaccination of May 4, 2010; she alleged, in essence, that W.R. was able to perform many tasks prior to his May 2010 vaccination that he subsequently lost after that vaccination.[38] (Ex. 276, p. 10, ¶¶ 47, 51.) Mrs. Rogero specifically recounted an alleged incident on May 29, 2010, while she observed W.R. playing, stating that W.R. would not turn his head to sound, or engage with her upon his name being called multiple times. (*Id.*, p. 13, ¶ 56.) She also described another incident occurring on May 30, 2010, at which time she observed that it was "extremely difficult" to get W.R. to make eye contact. (Ex. 40, p. 7 of 11, ¶ 43; Ex. 276, p. 14, ¶ 57.)

Mrs. Rogero stated that it is unknown if W.R. had a seizure after his DTaP vaccination of May 4, 2010, since W.R. slept in a separate room from his parents at that time. (Ex. 276, p. 11, ¶ 53.) However, she reported that W.R. experienced a "stiff episode" around September or October of 2011. (*Id.*, p. 13, ¶ 54.) [IN NEUROLOGY RECORD]

2. Affidavit of Walter Rogero, II

W.R.'s father, Walter Rogero II, signed an affidavit on August 13, 2012 (Ex. 41, pp. 9-11 of 11), but did not testify at the evidentiary hearing. Mr. Rogero's affidavit also contained statements that veered into medical opinion testimony, offering his own opinion regarding the medical and scientific issues that are central to this case.[39] As for *additional factual allegations* made in his affidavit, Mr. Rogero stated, that W.R. "lost many abilities" sometime after his DTaP vaccination of May 4, 2010, including "saying "ma" and "da," waving independently, and pointing." (*Id.*, p. 11 of 11, ¶ 24.) Moreover, he stated that, after W.R.'s DTaP vaccination of May 4, 2010, W.R.'s "immune responses to food" and his "eczema" increased. (*Id.*)

[HHS EXPERT DOCUMENTED FROM MEDICAL RECORDS LOSS OF SKILLS, ESPECIALLY POINTING AND 12 MONTHS OF LOSS OF SOCIAL/EMOTION SKILLS AS HE WAS NOT LONGER RESPONDING MAY-JUNE LIKE BEFORE]

3. Mrs. Rogero's evidentiary hearing testimony

Mrs. Rogero also testified extensively at the evidentiary hearing held in this case, on March 1 and 15, 2016. Mrs. Rogero's extensive testimony, among other things, included many instances in which she read from her own prepared notes,[40] or offered her own opinions

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[38] I note that Mrs. Rogero was **referring to W.R.'s initial developmental evaluation {MEDICAL RECORD] of January 27, 2010,** as reflected on Ex. 34, pp. 2-21, to **describe W.R.'s developmental condition before his vaccinations of May 4, 2010.** (Ex. 276, p. 10, ¶ 51; *see also* Ex. 34, pp. 2-21.) She ~~alleged~~ that W.R. lost many of the abilities that he had acquired prior to his DTaP vaccination, stating that, in the time period after May 4, 2010, W.R. specifically lost pointing, waving, turning to his name, and his ability to vocalize different sounds. (Ex. 276, p. 10, ¶ 51.) [STATING FINDINGS PRE AND POST OF MEDICAL FACT]

[39] *See* Ex. 41, p. 11 of 11, ¶ 28 (Mr. Rogero stating that W.R. "exhibited reactions to vaccines in keeping with known adverse effects to the individual vaccines at several points in his development" and that "[a]ccompanying these reactions were developmental losses").

[40] *E.g.*, Tr. 505 (Mrs. Rogero stating during her testimony that she was "just reading from my chronological history that I made"); Tr. 509 (Mrs. Rogero acknowledging that she was reading from prepared notes); Tr. 547 (Mrs. Rogero stating that she was essentially reading her prepared notes that consisted of a "chronological history of" or "highlights" of W.R.'s medical

[FILED IN ENTIRETY, EX A TO POST HEARING BRIEF TO THE COURT AFTER HEARING, OVER 200 APPOINTMENTS WITH DATES, EXHIBIT NUMBERS, AND RELATIVE CHRONOLOGICAL HISTORY]

regarding medical and scientific issues that are central to this case.[41] At other instances, Petitioners' counsel read excerpts from W.R.'s medical records, and solicited answers to leading questions asked of Mrs. Rogero.[42] Much of Mrs. Rogero's testimony, however, included statements in which she made allegations about W.R.'s symptoms or behavior. While I will further discuss Mrs. Rogero's testimony in Section XVII, below, in this section, I will simply list *additional factual allegations* made by Mrs. Rogero that are *at variance* with W.R.'s contemporaneous medical records. [

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records); Tr. 568 (Mrs. Rogero stating that she was reading excerpts "from her personal notes" regarding W.R.'s condition on October 6, 2010); Tr. 581 (Mrs. Rogero stating that she was reading excerpts comprised of "probably notes that I took from the medical records").

41 *E.g.*, Tr. 483-84 (Mrs. Rogero stating that W.R.'s doctor was in error when he assessed that W.R. failed one of his two-month developmental markers); Tr. 485-86 (Mrs. Rogero stating that W.R. had a "reaction" to her flu vaccination of November 25, 2008); Tr. 510 (Mrs. Rogero stating that W.R. started having slight symptoms of regression in June and July of 2009); Tr. 518 (Mrs. Rogero speculating as to whether W.R. had Guillian-Barre syndrome (GBS) in his first year of life); Tr. 544 (Mrs. Rogero interpreting certain excerpts from W.R.'s developmental assessment of July 8, 2010, for markers of encephalopathy) [IN PLEADINGS FROM COUNSEL]; Tr. 579 (Mrs. Rogero stating that "his only regressions in the past have been associated with vaccines"); Tr. 897 (Mrs. Rogero stating that the purpose of her rebuttal testimony was to "show in the contemporaneous medical records where regression happened"); Tr. 900 (Mrs. Rogero providing a definition of "ill" in an attempt to rebut Dr. Wiznitzer's testimony regarding W.R.'s condition at two months of age); Tr. 906 (Mrs. Rogero giving definitions of medical phenomenon such as "sluggish pupillary response" stated in W.R.'s contemporaneous medical records); Tr. 919-921, 924-27, 931-37 (Mrs. Rogero interpreting W.R.'s contemporaneous medical records for alleged instances of regression). [EXPERT MD DID THIS FOR THE MASTER]

42 As an example, Petitioners' counsel read from the following of W.R.'s medical records [FOR THE SPECIAL MASTER'S RECORD] while asking leading questions of Mrs. Rogero: Tr. 480-81 (W.R.'s birth records); Tr. 486-87 (W.R.'s doctor visit of December 3, 2008); Tr. 487-88 (W.R.'s doctor visit of January 3, 2009); Tr. 490-92 (W.R.'s doctor visit of Feb. 13, 2009); Tr. 492-93 (W.R.'s doctor visit of March 2, 2009); Tr. 497 (W.R.'s doctor visit of March 7, 2009); Tr. 497-98 (W.R.'s doctor visit of March 11, 2009); Tr. 499-500 (W.R.'s doctor visit of April 10, 2009); Tr. 500-01 (W.R.'s doctor visit of April 13, 2009); Tr. 501-02 (W.R.'s doctor visit of April 25, 2009); Tr. 503-04 (W.R.'s doctor visit of April 27, 2009); Tr. 504 (W.R.'s initial developmental evaluation of May 5, 2009); Tr. 505 (W.R.'s developmental therapy session of May 18, 2009); Tr. 506 (W.R.'s developmental therapy session of June 2, 2009); Tr. 507 (W.R.'s doctor visit of June 16, 2009); Tr. 510 (W.R.'s developmental therapy sessions in June and July 2009); Tr. 510 (W.R.'s medical visit of July 20, 2009); Tr. 515 (W.R.'s developmental therapy session of August 4, 2009); Tr. 516 (W.R.'s developmental therapy session of August 13, 2009); Tr. 519 (W.R.'s one-year well visit of September 24, 2009); Tr. 522-23 (W.R.'s 15-month well-visit of December 18, 2009); Tr. 562- 63 (W.R.'s developmental therapy session of August 25, 2010); Tr. 564 (W.R.'s doctor visit of September 29, 2010).

a. Allegations regarding the reliability of W.R.'s speech therapy records starting in March of 2010

Mrs. Rogero testified that, upon her examination of W.R.'s developmental therapy records, she was of the belief that certain of W.R.'s speech therapy evaluations were inaccurate. Specifically, she stated her belief that, starting in March of 2010, one of W.R.'s speech therapists, Rebecca Whistler, had apparently pre-filled W.R.'s speech therapy session notes *prior to* his actual therapy sessions. (*E.g.*, Tr. 526-27, 552, 897-98.) In essence, Mrs. Rogero alleged that Rebecca Whistler's notes regarding W.R.'s speech were not an accurate, contemporaneously-created accounting of his abilities at that time. (*Id.*) [HE HAD TWO THERAPISTS, THIS WAS NOTING THAT THE ONE WITH NOTES WERITTEN AFTER A SESSION WERE MORE EXACT THAN THE PRE-FILLED GOALS FOR ACCURACY, AS HE WAS POINTING INFEPENDENTLY IN RECORD, AND THIS WAS ON WAVING ABILITY DOCUMENTED WITH LOSS IN MAY 2010, NOT SPEECH CONFLICTING WITH OCCUPATIONAL THERAPIST RECORDS]

b. W.R.'s alleged symptoms following his DTaP vaccination in May 2010

Mrs. Rogero testified that, twenty-seven days after W.R.'s DTaP vaccination of May 4, 2010, she "really knew something was wrong" (Tr. 531), further stating that she was unable to get W.R. to make eye contact at that time (Tr. 531-32). At a later point in her testimony, she testified that she "knew something was linked to the vaccines as of September 2010." (Tr. 595.) At another time, Mrs. Rogero testified that W.R. started having problems with his sleep after his vaccinations administered during his first year of life. (Tr. 506.)

c. Allegations regarding Dr. Summar's consultation notes from April 2012

Mrs. Rogero testified that Dr. Summar's consultation notes, reflecting his examination of W.R. in April of 2012, did not fully document Dr. Summar's medical opinions from that visit. (Tr. 587-89.) In this regard, she alleged that Dr. Summar had agreed to submit his revised consultation notes from that visit, but that that request had remained pending as of the hearing. (Tr. 587-89.) [INCORRECT - FINAL REPORT WAS FILED PRIOR TO HEARING]

V

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

In this case, each side relies upon the expert reports and hearing testimony of medical experts. Overall, a total of 14 experts provided an expert opinion in this case, with nine of those experts providing an opinion on behalf of the Petitioners and five of those experts providing an opinion on behalf of the Respondent. The following nine experts provided a medical opinion on behalf of the Petitioners: (1) Mary Megson, M.D.; (2) Christopher Shaw, Ph.D.; (3) Judy Mikovits, Ph.D. and Francis Ruscetti, Ph.D.[43]; (4) Richard Deth, Ph.D.; (5) Lawrence Palevsky, M.D.; (6) Christopher Exley, Ph.D.; (7) Helen Ratajczak, Ph.D.; (8) Stephanie Seneff, Ph.D.; and (9) Suzanne Goh, M.D. On behalf of the Respondent, the following five experts provided a medical opinion in this case: (1) Andrew MacGinnitie, M.D., Ph.D.; (2) Jeffrey Johnson, Ph.D.; (3) Edward Cetaruk, M.D.; (4)

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[43] Drs. Mikovits and Ruscetti submitted a combined expert report in this case. (Ex. 236.) Thus, I have grouped them together in the discussion that follows.

Max Wiznitzer, M.D.; and (5) Bruce Cohen, M.D. At this point, I will briefly summarize both the qualifications and the opinions of those expert witnesses.

A. Petitioners' experts

1. Mary Megson, M.D.

a. Qualifications

Dr. Megson earned her Bachelor of Science (B.S.) in 1974 from Hollins College, and earned her Doctor of Medicine (M.D.) in 1978 from University of Virginia. (Ex. 105, p. 1; Tr. 11.) She completed her internship and residency at Boston Floating Hospital in 1981. (*Id.*) From 1981 to 1982, Dr. Megson completed her fellowship in ambulatory pediatrics at Boston Children's Hospital, and from 1988 to 1990, completed her fellowship in child development at the Medical College of Virginia. (*Id.*; Tr. 11-12.) She obtained board certifications from the National Board of Medical Examiners in 1979, and from the American Board of Pediatrics in 1983. (*Id.*)

Dr. Megson's notable past employment includes concurrently working within a health maintenance organization (HMO), from 1982 to 1984, while serving as a Clinical Instructor in Pediatrics at the Bowman Gray School of Medicine. (Ex. 105, p. 1.) From 1984 to 1988, she worked in private practice, and from 1990 to 1999, she served as the Director of Developmental Pediatrics at the Children's Hospital. (*Id.*) From 1997 to 2001, she was a Clinical Professor of Pediatrics at the Medical College of Virginia, rising to the rank of an Associate Clinical professor. (*Id.*) She has been in private practice since 1999. (*Id.*)

Dr. Megson is a member of the Society of Developmental Pediatrics and a fellow of the American Academy of Pediatrics. (Ex. 105, p. 1.)

She filed an expert report in this case on May 12, 2014. (Ex. 104.) Dr. Megson also testified at the evidentiary hearing held in Washington, D.C. on February 25, 2016. (Tr. 11-92.)

b. Summary of Dr. Megson's opinion **§ 300aa-11(c)(ii)(II).**

Dr. Megson opined that W.R. has certain genetic predispositions that made him "unable to detoxify" the aluminum adjuvants contained in some of his vaccines. (Ex. 104, pp. 7-10 of 10, Tr. 55.) She specifically pointed to the "pertussis" portion of the DTaP vaccination administered to W.R. at 19-months of age, opining that that vaccination caused an "increased transport of aluminum to the brain," which eventually caused "developmental regression" and "encephalopathy." (*Id.*) She further opined that, in W.R.'s case, "each vaccination caused chronic oxidative stress in an already weakened system," manifesting in symptoms such as "chronic diarrhea," "eczema," "allergies," "progressive hypotonia," "motor delays," "dyspraxia," and "encephalopathy." (Ex. 104, p. 9 of 10.)

Dr. Megson pointed to two distinct time periods in W.R.'s early years of life -- time periods during which she deemed the "most profound and immediately obvious regressions" occurred in W.R. (Ex. 104, p. 9 of 10.) She pointed (1) to the time period *after* his two-month vaccinations, in which she opined that W.R. had an "onset of eczema" -- a symptom she deemed was "a typical aluminum reaction," and (2) to the time period *after* his DTaP vaccination at 19

months of age, during which, according to Dr. Megson, W.R. suffered from "developmental regression." (*Id.*)

Dr. Megson stated that W.R.'s "clinical course" supported her theory (Ex. 104, p. 7 of 10), but in this regard she primarily relied on the *parental testimony*, describing symptoms allegedly suffered by W.R. immediately after each set of his administered vaccinations during his early years of life (*id.*, p. 1). **[DR. MEGSON QUOTED THE MEDICAL RECORDS SAME AS PARENTAL TESTIMONY, SEE ACTUAL RECORDS AND SM CONCESSION OF USING RECORDS AT 46a Top Line]**

In addition, Dr. Megson referenced several of W.R.'s nonspecific laboratory testing results from his medical records -- *i.e.*, his "decreased folic acid derivatives," low "IGF," low "B_{12} levels," and "high glutamate" -- as apparent support for her theory (Ex. 104, p. 7), but provided very limited explanation as to *how exactly* those disparate test results allegedly support her overall causation theory in this case (*id.*, pp. 7-10). Moreover, she provided a strong opinion that W.R. was "exquisitely sensitive to aluminum" (*id.*, p. 8) -- primarily relying on W.R.'s patch testing results reflecting that W.R. had "positive skin reactions to 17/20 foods placed under aluminum foil against the skin" (*id.*) -- but provided limited explanation as to *why* Dr. Megson viewed those testing results to be conclusive with regards to W.R.'s apparent aluminum sensitivities.

As to *how* the aluminum in the vaccines allegedly caused W.R.'s regression and encephalopathy, Dr. Megson's presentation was not clearly set forth, but she mentioned one possible factor. In this regard, she pointed to the fact that W.R. has a variant in two of his genes -- a "CCL_2 heterozygous gene variant" and a "homozygous SNP" variant for the "monocyte chemoattractant protein-1" -- opining that those variants, in combination with aluminum adjuvants in his administered vaccinations, "overwhelmed his detoxification pathways," allowing for an "increased transport of aluminum into the brain," and thus, "inducing encephalopathy." (Ex. 104, p. 7 of 10.)

2. Christopher Shaw, Ph.D.

a. Qualifications

Dr. Christopher Shaw earned a B.S. in Biology from the University of California Irvine in 1971. (Ex. 87, p. 1; Tr. 94.) He earned his Master of Science (M.S.) in Physiology in 1974, and his Ph.D. in Neurobiology in 1979, both from the Hebrew University of Jerusalem. (*Id.*) From 1979 to 1985, Dr. Shaw was a postdoctoral fellow ("PDF") at Dalhousie University, subsequently serving as a Research Associate at that same university from 1986 to 1988. (Ex. 87, p. 1.) From 1988 to present, Dr. Shaw has been a faculty member at the University of British Columbia, Faculty of Medicine, in the Department of Ophthalmology and Visual Sciences, rising to the position of Professor since 2004. (Ex. 87, p. 1; Tr. 94.)

Dr. Shaw's *curriculum vitae* reflects that his research focuses on the areas of neuroplasticity and neuropathology, with his current research focusing on "ALS-parkinsonism dementia complex (ALS-PDC)," a neurological disorder. (Ex. 87, p. 15; Tr. 95.) His *curriculum vitae* lists that he has co-authored approximately 140 peer-reviewed articles and 164 abstracts, and has also authored three books. (Ex. 87, p. 17; Tr. 96; *see also* Ex. 87, pp. 17-35.) He has served as a reviewer for several scientific journals, and has also served as an editor for several book chapters and books. (Ex. 87, pp. 17-35.)

Dr. Shaw filed an expert report in this case on September 27, 2013. (Ex. 86.) He also testified, by telephone, at the evidentiary hearing held in Washington, D.C. on February 25, 2016. (Tr. 93-146.)

b. Summary of Dr. Shaw's opinion

Dr. Shaw mainly provided testimony on the *general* causation issue in this case, on the "potential for aluminum in vaccines to damage the nervous system in some susceptible individuals" (Tr. 96), and on the "*possible role* aluminum adjuvants in vaccines might play" in causing "the range of developmental and other disorders experienced by [W.R.]" (Ex. 86, p. 1, emphasis added).

His causation theory in this case was difficult to follow and extremely tentative, but the crux of his opinion can be summarized as follows: (1) aluminum is a "neurotoxic" compound (Tr. 96-98), and an elevated amount of "aluminum exposure" can cause "aluminum neurotoxicity" (Ex. 86, p. 3; Tr. 130); (2) the amount of aluminum exposure necessary to cause such an "aluminum neurotoxicity" can come from various sources, including "from the various pediatric vaccines" that W.R. received in the early years of life (Ex. 86, p. 3; Tr. 130); (3) certain individuals are especially susceptible to the "neurotoxic" effects of aluminum due to genetic predispositions that render them unable to excrete aluminum from their bodies (Tr. 100); (4) W.R. had one such variant -- the CCL2 gene variant -- that could render him more susceptible to the harmful effects of aluminum (Tr. 101); and (5) W.R.'s diagnoses of "ASD and other system disorders" could possibly arise due to the effects of "aluminum neurotoxicity" (Ex. 86, p. 3; Tr. 130). Dr. Shaw relied heavily on a perceived *close temporal relationship* between W.R.'s vaccinations and the onset of his neurological disorders, reasoning that "it is clear from my reading of the material provided about [W.R.] that the various disorders, including ASD, followed *after* the vaccinations." (Ex. 86, p. 3, emphasis in original.)

3. Judy Mikovits, Ph.D., and Frank Ruscetti, Ph.D.

On September 28, 2015, Petitioners' filed an expert report said to be co-authored by Drs. Judy Mikovits and Frank Ruscetti, though only Dr. Mikovits signed the report. (Ex. 236). Dr. Mikovits also testified at the evidentiary hearing held in Washington, D.C. on February 26, 2016 (Tr. 153-211), and on March 15, 2016 (Tr. 948-986).

a. Qualifications - Judy Mikovits, Ph.D.

Dr. Mikovits earned her Bachelor of Arts (B.A.) in Biology, with a specialization in Biochemistry, from the University of Virginia in 1980. (Ex. 237, p. 4; Tr. 154.) She earned her Ph.D. in Biochemistry and Molecular Biology from George Washington University in 1991.[44] (Tr. 154.)

From 1992 to 1994, Dr. Mikovits was a post-doctoral fellow in Molecular Virology at the National Cancer Institute, Lab of Genomic Diversity, subsequently serving as a staff scientist at the National Cancer Institute, Lab of Leukocyte Biology, from 1994 to 1998. (Ex. 237, pp. 3-4.) From 1999 to 2001, she served as a Lab Director at the Laboratory of Antiviral Drug

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[44] The dates of her B.A. and Ph.D. are not provided in her CV.

Mechanisms, a division of the National Cancer Institute. (*Id.*, p. 3; Tr. 156.) Dr. Mikovits worked in various capacities at several biotechnology start-up companies from 2002 to 2006, and was the Research Director of the Whittemore Peterson Institute for Neuro-Immune Disease (WPI) from 2006 to 2011. (Ex. 237, pp. 2-3.) From 2006 to 2012, she served as a scientist and consultant for a pharmaceutical company. (*Id.*, pp. 1-2.) She currently is a consultant for MAR Consulting, a consulting group she co-founded, and serves as an advisor for a private equity investment company. (*Id.*) Her *curriculum vitae* lists 51 publications that she has co-authored. (*Id.*, pp. 5-9.)

b. Qualifications - Frank Ruscetti, Ph.D.[45]

Dr. Ruscetti received his B.S. in Biology in 1968 from Boston University, and his Ph.D. in Microbiology from the University of Pittsburgh in 1972. (Ex. 238, p. 1.) From 1972 to 1975, Dr. Ruscetti was a Research Instructor at the University of Pittsburgh, School of Medicine. (*Id.*) From 1975 to 1978, Dr. Ruscetti worked for a private company, and since 1978, has held various senior positions at the National Cancer Institute (NCI). (*Id.*, pp. 1-2.) He currently serves as the Principal Investigator for NCI's Leukocyte Biology Section, and has been an Adjunct Professor of Biochemistry and Molecular Biology at George Washington University -- a position he has held since 1988. (*Id.*)

Dr. Ruscetti has co-authored more than 300 scientific publications, served on editorial boards of several scientific journals and is currently on the editorial board for *Stem Cells*. (Ex. 238, pp. 2-32.)

As discussed above, although Drs. Ruscetti and Mikovits are said to have co-authored an expert report (Ex. 236), Dr. Ruscetti did not testify at the evidentiary hearing.

c. Summary of Dr. Mikovits' and Dr. Ruscetti's expert report

Ex. 236, as previously noted, was referenced by Petitioners as the joint opinion of Drs. Mikovits and Ruscetti, but was *signed only by Dr. Mikovits.*[46] The report is somewhat curious, as it in part discusses the specific case of W.R. (Ex. 236, pp 1-5, 11-19 of 19) and seems to *imply* that W.R. was injured by his vaccinations, but never actually *states directly* that W.R. himself has any vaccine-caused injuries (*e.g.*, *id.* at p. 19 of 19). Further, the "Theory" section of the report is a vague discussion suggesting that disruptions of a person's immune system early in life can result in "long-term consequences to the immune and neuronal systems" (p. 6), *but does not focus on vaccinations* as a possible source of such disruptions (pp. 6-10).

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[45] As will be explained below, it is unclear to what extent, if any, Ex. 236 represents the views of Dr. Ruscetti, rather than simply those of Dr. Mikovits. However, in the interest of completeness, I will summarize the qualifications of Dr. Ruscetti.

[46] In my analysis of this case, I have *assumed* that Dr. Ruscetti co-authored Ex. 236. Even under this assumption, I find that the report offers scant support to Petitioners' overall causation case, and was heavily outweighed by contrary reports and testimony of Respondent's experts.

d. Dr. Mikovits' opinion at the hearing

Dr. Mikovits' opinion stated during the evidentiary hearing was never clearly or coherently explained, but as I understand it, her opinion can be summarized as follows. Dr. Mikovits opined that, due to certain genetic susceptibilities in W.R., his vaccinations triggered a "cytokine storm" (Tr. 174) that sent his immune system into a "state of chaos" (Tr. 199), resulting in ongoing "inflammation" due to an overstimulation of his immune system (Tr. 204). She opined that the vaccine-induced overstimulation of W.R.'s immune system had "profound long term effects on [W.R.'s] innate and adaptive immune system" (Ex. 236, p. 6), pointing to W.R.'s "innate immune system" as being particularly negatively affected -- the aspect of the immune system that she deemed was responsible for brain development (Ex. 236, p. 19; *see also* Tr. 188-89). In this regard, Dr. Mikovits opined that due to the apparent harm to W.R.'s "innate immune system," W.R. developed an "autoimmune response" (Tr. 165-66), which, in turn, caused ~~numerous neurodevelopmental~~ issues in W.R., such as "mitochondrial dysfunction" (Tr. 195), "encephalopathy," "hypotonia," "myelitis," and "inflammation of the muscles" (Tr. 200).[THE MASTER ADDS NEURODEVELOPMENTAL TO ALL MEDICAL DIAGNOSES OVER 12 TIMES IN THE DECISION, INCORRECT FACTUAL INFERENCES UNSUPPORTED BY THE RECORD]

Aside from those general points, the precise scope of her expert testimony seemed to shift throughout the litigation, often veering into opinions concerning medical disciplines in which she was wholly unqualified. My understanding of her very unclear opinion in this case, however, is that Dr. Mikovits relied on a few critical premises for her expert opinion. One premise was that W.R. suffered a significant immune reaction" to his vaccinations on November 19, 2008, thus triggering an overstimulated "inflammatory" response in W.R., which was "not resolved at the time of subsequent vaccinations" (Ex. 236, p. 11). A second premise upon which Dr. Mikovits relied for her theory was the assertion that, *each time* W.R. was given vaccinations, he developed numerous symptoms indicative of an ongoing inflammatory response and immune system dysfunction. (*E.g.*, Ex. 236, pp. 4, 12, 13.)

4. Richard Deth, Ph.D.

a. Qualifications

Dr. Deth received his B.S. in Pharmacy from the State University of New York at Buffalo in 1970, and his Ph.D. in Pharmacology from the University of Miami School of Medicine in 1975. (Ex. 224, p. 1; Tr. 277.) He completed his post-doctoral training at the Catholic University of Leuven (Belgium) in 1976. (*Id.*)

Dr. Deth was a registered pharmacist from 1972 to 1976. (Ex. 224, p. 1; Tr. 277.) Starting in 1976, he held various faculty positions at Northeastern University, serving as a Professor of Pharmacology for many years beginning in 1987. (*Id.*)[47] He is currently a Research Professor at Florida Atlantic University, a position he has held since 2013, and is also concurrently a Professor of Pharmacology at Nova Southeastern University since 2014. (*Id.*)

[47] Dr. Deth's CV lists that from "1987-Present," he has been a "Professor of Pharmacology." (Ex. 224, p. 1.) His CV is unclear, however, concerning the academic institutions at which he served as a "Professor of Pharmacology" between 1987 and 2013. (*Id.*)

Dr. Deth is currently on the scientific advisory boards of Autism Research Institute and Immunotec Inc., and previously served on the board of the National Autism Association. (Ex. 224, p. 2.) His *curriculum vitae* lists that he has co-authored 100 scientific articles, authored a monograph, and holds four patents for methods of diagnosing schizophrenia. (Ex. 224, pp. 2-11; Tr. 278.)

Dr. Deth's first report was filed on January 2, 2015 (Ex. 149), and his revised expert report was filed on October 23, 2015 (Ex. 242). He also testified at the evidentiary hearing held in Washington, on February 29, 2016. (Tr. 276-378.)

b. Summary of Dr. Deth's opinion

Dr. Deth's opinion in this case was very unclear and difficult to follow, and he seemed to contradict himself as to the precise scope of his opinion. For instance, in his expert report and hearing testimony, Dr. Deth seemed at times to provide not only a *general causation* opinion (*i.e*, that the types of vaccinations given to W.R. *can* cause the *types* of developmental delays from which W.R. suffers), but also a *specific causation* opinion (*i.e*, that the vaccinations received by W.R. *did* cause W.R.'s own developmental delays). (*E.g.*, Ex. 242, p. 2; Tr. 348-60.) At other instances, however, Dr. Deth testified that he was only addressing the *general* causation issue in this case, stating that his opinion was limited to opining on the "molecular perspective of neurodevelopment," and not to how that theory applies to the case of W.R. (*E.g.*, Tr. 362.)

The crux of Dr. Deth's apparent theory can be summarized as follows: (1) a cellular process called "methylation" plays a critical role in "guiding normal development" (Ex. 242, p. 2); (2) a combination of W.R.'s "genetic risk factors" (Tr. 361), and his laboratory testing revealing low levels of a compound called "insulin-like growth factor-1" ("IGF-1") that "promotes methylation" (Ex. 242, p. 2), combined to place W.R. at an increased risk for "impaired methylation" (Tr. 361); (3) W.R.'s vaccinations significantly aggravated his already impaired "methylation" process (Ex. 242, p. 2), by promoting a phenomenon called "oxidative stress" -- a phenomenon that also leads to "impaired methylation" (Ex. 242, p. 22); and (4) W.R.'s significantly impaired methylation, aggravated by his vaccinations in the early years of life, in turn, caused a "material and substantial contribution" to W.R.'s "impaired development." (Tr. 361). Thus, Dr. Deth opined that W.R.'s vaccinations in the early years of his life were "an important contributing factor to the encephalopathy that in [W.R.]'s case manifested itself as neurodevelopmental delay and autism." (Ex. 242, p. 22.)

Although Dr. Deth stated at one point during the evidentiary hearing that his theory was limited to the "molecular perspective of neurodevelopment" (Tr. 362), he also stated in his expert report that W.R.'s clinical record "provides clear evidence of sporadic episodes of decreased physical growth which correspond to time intervals following vaccinations" (Ex. 242, p. 22). Moreover, he stated that W.R.'s underlying "oxidative stress" and "impaired methylation" induced by his vaccinations also resulted in additional clinical features of "mitochondrial dysfunction," "autoimmune activation," and an "abnormal GI function" -- deeming those clinical features to be reflective of the "additional sequelae of oxidative stress." (Ex. 242, p. 22.) At the evidentiary hearing, however, he walked back his statements regarding references to W.R.'s "clinical record," testifying that he essentially relied on a chart retrospectively prepared by Mrs. Rogero about W.R.'s growth -- *i.e.*, a chart not within W.R.'s medical records. (Tr. 348-49.) Similarly, he testified that he relied on Dr. Civitello's letter, Ex.

102, as support for his statements that W.R.'s "medical records" provided "evidence of vaccine-associated developmental delay" (Tr. 361), instead of making his *own assessment* of W.R.'s *contemporaneous* medical records.

5. Lawrence Palevsky, M.D.

a. Qualifications

Dr. Palevsky received his A.B. degree from Vassar College in 1983, and his M.D. from the New York University School of Medicine in 1987. (Ex. 244, p. 2; Tr. 444.) From 1987 to 1990, he completed his internship and residency in pediatrics at the Mount Sinai Medical Center, subsequently completing a fellowship in ambulatory care pediatrics in 1991 at Bellevue Hospital-New York University School of Medicine. (*Id.*)

Dr. Palevsky held various positions at New York Medical College from October 1991 to June 1995, serving as an Assistant Professor at the Department of Pediatrics and as an Assistant Professor at the Department of Emergency Medicine. (Ex. 244, p. 2.) From July 1995 to May 2000, he served in various positions at Lenox Hill Hospital, an affiliate of the New York University School of Medicine, notably serving as Chief of the Pediatric Acute Care Unit. (*Id.*, p. 1; Tr. 445.) From January 1994 to June 1996, Dr. Palevsky also concurrently served as an Adjunct Clinical Instructor at the Mount Sinai School of Medicine, Department of Pediatrics. (Ex. 244, p. 1.) Starting in May 2000, he has held several positions as a pediatrician and medical consultant at various "holistic health" pediatric practices. (Ex. 244; Tr. 445.)

Dr. Palevsky has made several medical appearances and given numerous lectures on the safety and efficacy of vaccines and holistic medicine. (Ex. 244, pp. 3-5.) He was a Fellow at the American Academy of Pediatrics and has held leadership positions within several holistic care medical associations. (*Id.*, p. 3.) Since 2004, he has served as a member of the Medical Advisory Board of the Developmental Delay Resources. (*Id.*) Dr. Palevsky was a board-certified pediatrician from November 1990 to December 2011, but is currently not board-certified. (*Id.*)

Dr. Palevsky filed an expert report on October 26, 2015. (Ex. 243.) He also testified at the evidentiary hearing held in Washington, D.C. on March 1, 2016. (Tr. 444-478.)

b. Summary of Dr. Palevsky's opinion

Dr. Palevsky stated that the purpose of his expert opinion in this case was to simply "present a *plausible* reason for how [MECHANISM] the vaccines *may have* contributed to [W.R.'s] current state of neurodevelopment." (Tr. 447, emphasis added.) His testimony was very vague and difficult to follow, but as I understand it, his opinion is as follows. Dr. Palevsky opined that W.R.'s brain development was disrupted after various components from his vaccinations, including "polysorbate 80" and "aluminum adjuvant nanoparticles" (Tr. 457), breached the "blood-brain barrier" -- the mechanism that normally protects the brain "from most materials that circulate in the bloodstream" (Tr. 455). (*See also* Ex. 243, pp. 8-10; Tr. 454-465, 476.) Moreover, he opined that the harmful materials that entered W.R.'s brain caused an inflammation in his brain, thus leading to W.R.'s various neurodevelopmental disorders, such as "chronic encephalopathy," "developmental delays," and "regression." (Ex. 243, pp. 4-5.)

As to *how* W.R.'s ~~neurodevelopmental condition~~ was caused by his vaccinations, Dr. Palevsky's theory was vague, but seemingly focused on the state of W.R.'s immune system at two months of age. (Tr. 462-65.) He seemed to opine that, at two months of age, W.R. already had a severely challenged immune system, as indicated by "an elevated level of inflammation" shown by his symptoms of "eczema" and "increased mucous production" (Tr. 463) -- elevated levels of inflammation that significantly increased due to W.R.'s first set of vaccinations in November of 2008 (Tr. 462-64), thus triggering a "cycle of chronic inflammation" (Tr. 464). Regarding this "cycle of inflammation," Dr. Palevsky seemed to indicate that, immediately after his first set of vaccinations, W.R. showed delays due to his then-present high levels of inflammation, followed by a period of time when W.R. "started to improve," but then continued to "show significant signs of inflammation through most of his first couple years of life" due to his continued exposure to vaccinations containing inflammation-inducing materials. (Tr. 464.) Dr. Palevsky also indicated that materials in W.R.'s vaccinations, especially "polysorbate 80" and "aluminum adjuvant nanoparticles," contributed to a heightened level of inflammation in W.R.'s body and brain (Tr. 410), but how those materials allegedly did so was never clearly explained. [AGAIN, THE MASTER ADDS NEURODEVELOPMENTAL TO ACTUAL RECORD THAT STATES ENCEPHALAOPTHY, TO MOST ALL EXPERTS, THERE IS NO CLAIM OF NEURODEVELOPMENTAL AUTISM AS AN INJURY]

6. Christopher Exley, Ph.D.

a. Qualifications

Dr. Exley received his Ph.D. in Ecotoxicology of Aluminum, from the University of Stirling.[48] (Ex. 100, p. 1; Tr. 648.) He has written several book chapters and published over 100 articles regarding the potential harmful effects of aluminum. (Ex. 100, pp. 1-8; Tr. 651-52.) He is currently a Professor of Bioinorganic Chemistry at Keele University in Staffordshire, United Kingdom. (Ex. 100, p. 1; Tr. 650.)

Dr. Exley filed an expert report on October 1, 2013. (Ex. 99.) He also testified at the evidentiary hearing held in Washington, D.C. on March 14, 2016. (Tr. 647-713.)

b. Summary of Dr. Exley's opinion[49]

Dr. Exley seemed to limit his opinion in this case to the *general causation* issue, simply providing mere *possibilities* as to the "question of how an aluminum adjuvant administered in a vaccine *might* bring about an adverse event in a recipient." (Ex. 99, p. 1 of 4, emphasis added.) His overall theory [REPORT ONLY STATES MECHANSIM] was that aluminum adjuvants contained in vaccines are "biologically reactive" (Tr. 654), and thus have the potential to cause harm once injected into the body (Ex. 99, pp. 1-3 of 4; Tr. 654-56). He stated three possibilities [EXPRESSED AS 'MECHANISM'] in his expert report as to how aluminum adjuvants could be harmful once injected into the human body via vaccinations: (1) that the aluminum in

[48] The dates of Dr. Exley's B.S. and Ph.D. are not listed within his CV, and were not provided during his evidentiary hearing testimony.

[49] I note that I am well aware of the fact that throughout Dr. Exley's expert report and testimony, he spelled "aluminum" with an alternative British spelling of "aluminium." (*See* Ex. 99, pp. 1-3.) For convenience's sake, however, I will use the standard American spelling of "aluminum" throughout this section and the discussion to follow, including when quoting certain portions of Dr. Exley's expert report and testimony.

adjuvants, either through a single vaccine or through multiple vaccines, accumulates in the body until a critical threshold of aluminum is reached triggering "aluminum-related" negative effects (Ex. 99, p. 2); (2) that the "immediate response" to the aluminum adjuvant causes the immune system to trigger a response mirroring the strong response of a "fully blown disease," thus triggering a "cascade of events throughout the body" in response to the aluminum (Ex. 99, pp. 2-3); and (3) that the inherent "potency" of the aluminum adjuvant causes the aluminum adjuvant to "'turn' almost anything into an antigen," thus causing "immune-like reactions" wherever aluminum may be in the body (Ex. 99, p. 3).

Dr. Exley seemed to acknowledge, however, that his general causation opinion in this case was still at an experimental level (Tr. 703-04), with his expert report simply serving as an argument as to why researchers should "now undertake research to understand how aluminum adjuvants actually work" (Ex. 99, p. 3). In this regard, he admitted as follows:

> The scientific literature pertaining to the toxicity of aluminum in humans is not as yet sufficiently developed to allow for direct cause and effect relationships in relation to [W.R.]'s exposure to aluminum, through vaccinations, and his medical conditions.

(Ex. 99, p. 3.)

*7. **Helen Ratajczak, Ph.D.***

*a. **Qualifications***

Helen Ratajczak received her B.S. in Chemistry, M.S. in Agricultural Biochemistry and Nutrition, and Ph.D. in Molecular Biology, all from the University of Arizona.[50] (Ex. 103, p. 1; Tr. 621-22.) Her notable employment experience include being a Research Associate at the University of Pittsburgh in the Department of Surgery from 1980 to 1981, and an Assistant Professor in the Department of Pathology at the Loyola University Stritch School of Medicine from 1981 to 1983. (Ex. 103, p. 1.) She currently serves as an Adjunct Associate Professor at the Illinois Institute of Technology's Department of Biology -- a position she has held since 1994. (*Id.*; Tr. 623.)

Dr. Ratajczak served in various immunology research roles from 1990 to 1998, rising to be the Group Leader of Immunology at the Illinois Institute of Technology Research Institute. (Ex. 103, p. 1.) Dr. Ratajczak served as a Senior Scientist in the Toxicology and Safety Assessment Department at a private pharmaceutical company from 1999 until 2006. (*Id.*; Tr. 623.) She has been involved in autism research since 2002, with particular interests in autism drug discovery proposals and the objective measures of autism. (Ex. 103, p. 1; Tr. 624.)

Dr. Ratajczak has co-authored more than 80 scientific publications and presentations. (Ex. 103, pp. 2-10.) She is a member of several scientific organizations, notably the Autism Society of America, the American Association of Immunologists, and the Society of Immunotoxicology. (*Id.*, pp. 1-2.)

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50 The dates of Dr. Ratajczak's academic degrees are not listed in her CV.

Petitioners filed Dr. Ratajczak's first written report on October 11, 2013 (Ex. 101), and a second report on January 6, 2015 (Ex. 216). She also testified at the evidentiary hearing held in Washington, on March 14, 2016 (Tr. 621-646).

b. Summary of Dr. Ratajczak's opinion

Dr. Ratajczak's overall theory seemed to be that it is "biologically plausible" that W.R.'s vaccinations could have weakened his "blood-brain barrier" and allowed for harmful materials from his vaccinations to enter his brain, thus causing "inflammation" that eventually led to neurological damage. (Ex. 216, pp. 1-4 of 5; Tr. 628-630.) As to *how* W.R.'s "blood-brain barrier" might have been weakened, she opined that due to the "many antigens" contained in vaccinations, the cumulative effect of the administration of numerous vaccinations administered at the same time caused a "tremendous immune response" in W.R. -- a tremendous immune response, which, in turn, caused his "blood-brain barrier" to be weakened. (Ex. 216, p. 1; *see also* Tr. 628-30).

Moreover, she pointed to W.R.'s "C677T MTHFR" gene variant, opining that that variant "*could have* affected the development of his immune system." (Ex. 216, p. 1, emphasis added.) In this regard, she opined that W.R.'s symptoms at two months of age, such as his "cough," "congestion," "sneezing," "green nasal discharge," and "cradle cap" were reflective of W.R.'s already weakened immune system due to his "C677T MTHFR" gene variant at that time. (*Id.*, pp. 1-2). Dr. Ratajczak opined that an individual's immune system is "particularly sensitive at two months of age." (Ex. 216, p. 2; Tr. 632, 633-35.) In this regard, she indicated that, soon after W.R.'s vaccinations of November 19, 2008, "tremendous developmental delay * * * set in" on W.R., and that such developmental delay was "quite profound" (Tr. 633) -- seemingly *contradicting* certain testimony given by other of Petitioners' experts in this case, opining that W.R. underwent a *gradual regression* after his first set of vaccinations.

Beyond that general framework, however, it was unclear what *exactly* Dr. Ratajczak's opinion was in this case, as her opinion shifted throughout this litigation. For instance, although her expert report explicitly stated that she was opining on the "many theories of causation of autism" (Ex. 216, p. 1), and the "biological plausibility of the cause of autism for [W.R.]" (*id.*, p. 2), at the evidentiary hearing she shifted her opinion as to the *exact injury* that W.R. suffered from, now stating, without elaboration, that W.R.'s vaccinations caused an "encephalopathy" (*e.g.*, Tr. 628, 630-31). [SHE STATES THAT AUTISM IS A SEQUELA OF ENCEPHALOPATHY IN RECORD]

Similarly, she opined that *Mrs. Rogero's* flu vaccination of November 26, 2008, also negatively harmed W.R., since he was exposed to the mercury contained in Mrs. Rogero's flu vaccination through breastfeeding, but failed to provide any specifics as to how that effect could come about. (Tr. 631-634.) Instead, she stated, without explanation or elaboration, that W.R. underwent "even more developmental delay and regression" after his mother's flu vaccination of November 26, 2008. (Tr. 634.)

8. Stephanie Seneff, Ph.D.

a. Qualifications

Dr. Seneff received her B.S. in Biophysics in 1968, her Masters of Science in Electrical Engineering in 1980, and her Ph.D. in Electrical Engineering and Computer Science in 1985, all

from the Massachusetts Institute of Technology (MIT). (Ex. 89, p. 1.) From 1985 to present, she has been at MIT's Computer Science and Artificial Intelligence Laboratory, currently serving as a Senior Research Scientist. (*Id.*, pp. 1-2.) Dr. Seneff has published numerous articles in technical journals, written two book chapters, and has presented at several conferences in her field of specialty of electrical engineering and computer science. (*Id.*, pp. 4-22.) Her *curriculum vitae* also reflects, however, that she has co-authored several articles concerning the topics of aluminum exposure and autism -- *i.e.*, topics that are *not* within her field of specialty. (Ex. 89.)

Dr. Seneff filed an expert report on September 27, 2013 (Ex. 88), but did not testify at the evidentiary hearing in Washington, D.C.

b. Summary of Dr. Seneff's opinion

Dr. Seneff opined that W.R. "suffered from extensive damage to the brain," "digestive tract," and "skeletal muscles," mainly due to an "exposure to toxic levels of aluminum" from the series of vaccinations that W.R. received in the early years of his life. (Ex. 88, p. 1 of 7.) She pointed to W.R.'s gene variant in the "MTHFR gene," attributing that variant as causing an impairment in W.R.'s "ability to detoxify aluminum" (*id.*, p. 2), which, according to Dr. Seneff, allowed for aluminum "to infiltrate the brain and damage neurons" (*id.*). Moreover, she opined that, due to this phenomenon of aluminum infiltrating the brain, a "low-grade encephalopathy" (*id.*, p. 5) was triggered in W.R., thus causing "brain damage and subsequent manifestations of delayed neurobehavioral development" (*id.*).

As support for her theory, Dr. Seneff cited to several of her *own articles* in her expert report, stating that "excess exposure to aluminum" could lead to a "chronic low-grade encephalopathy that would slowly damage the brain." (Ex. 88, p. 2.)[51]

Dr. Seneff's expert report also veered into opining on medical specialties in which she was wholly unqualified to provide an expert opinion. For instance, despite the fact that she is not a medical doctor, Dr. Seneff provided numerous *clinical assessments* of W.R., diagnosing W.R. with, among other things, "developmental regression" following his 19-month DTaP vaccination (Ex. 88, p. 2), "mitochondrial dysfunction" (*id.*, p. 3), and "chronic low-grade encephalopathy" (*id.*, p. 5) -- all diagnoses she opined to be due to aluminum exposure from vaccinations (*id.*, pp. 2-5). In this regard, she provided broad-sweeping conclusions, without further explanation or elaboration, asserting that W.R.'s "medical records are a "textbook example" of the consequences of acute exposure due to multiple simultaneous vaccinations." (*Id.*, p. 5.)

9. Suzanne Goh, M.D.

a. Qualifications

Dr. Goh received her B.A. in History and Science from Harvard University in 1997, and her M.D. from Harvard Medical School in 2004. (Ex. 225, p. 1.) She completed her internship in

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[51] Dr. Seneff's expert report also cited her articles generally, stating that aluminum is a "key contributor to the adverse reactions associated with vaccines," and that aluminum could also be a "potential contributor to the current autism epidemic." (Ex. 88, p. 2)

Pediatrics at the Massachusetts General Hospital in 2005, and her residency in Pediatric Neurology from the University of California, San Francisco in 2008. (*Id.*) Thereafter, she completed her postdoctoral research fellowship in 2009, and her postdoctoral clinical fellowship in 2011, both from Columbia University, College of Physicians & Surgeons, Division of Child and Adolescent Psychiatry. (*Id.*) She is board-certified in Neurology, with a special qualification in Child Neurology. (*Id.*)

Dr. Goh was an Attending Neurologist at the Columbia University Medical Center from 2009 to 2012. (Ex. 225, p. 1.) From July 2011 to December 2012, she concurrently served as an Assistant Professor of Clinical Neurology at Columbia University College of Physicians & Surgeons, and as a Co-Director of the Developmental Neuropsychiatry Program for Autism and Related Disorders at that same institution. (*Id.*) From 2013 to present, she has been a pediatric neurologist in private practice, concurrently working as an author and co-developer of the Autism Spectrum Disorder (ASD) Language curriculum. (*Id.*) She has co-authored six books, one book chapter, eight peer-reviewed articles, and two case reports. (*Id.*, pp. 2-4.)

Dr. Goh filed an expert report on January 2, 2015 (Ex. 150), but did not testify at the evidentiary hearing.

b. Summary of Dr. Goh's opinion

Dr. Goh's written opinion was extremely short and speculative in nature, and merely stated her view that "a disturbance of mitochondrial function" was a "*potential* theory of causation" in this case. (Ex. 150, p. 1, emphasis added.) In this regard, she seemed to opine that W.R. potentially had an "impaired mitochondrial function" (Ex. 150, p. 1) due to certain "underlying vulnerability" (*id.*, p. 2), but provided very little explanation as to *why* she held that belief. Similarly, her expert report was unclear as to the precise scope of her opinion, providing vague statements as to the *exact injuries* that she alleged were caused by W.R.'s vaccinations. [REPORT STATES VACCINE-RELATED BRAIN INJURY USING NEUROLOGY RECORDS, EX. 5 at 5 PEDIATRICIAN WITHELD 2 VACCINES DUE TO OPINE OF MITOCHONDRIAL DYSFUNCTION CONFIRMED BY HOSPITAL LABS AND SPECIFICALLY STATES BEFORE AND AFTER FROM MEDICAL RECORDS]

Dr. Goh's expert report cited some studies that purportedly provided support for her view that the "[i]mpaired function of mitochondria" is a "factor in numerous human diseases, including Autism Spectrum Disorders" (Ex. 150, p. 1), but failed to provide further elaboration on those statements. Similarly, her expert report attempted to provide "several mechanisms by which vaccines may lead to brain injury in those who have an underlying vulnerability in mitochondrial function" (*id.*), listing an "inflammatory response" and "aluminum neurotoxicity" as two possible mechanisms (*id.*, pp. 1-2), but did not take a position on what mechanism would be more likely in W.R.'s case.

Importantly, Dr. Goh relied on *parental assertions* concerning W.R.'s condition, before and after his 19-month DTaP vaccination, to provide support for her opinion that W.R.'s case points to "mitochondrial impairment exacerbated by vaccination." (Ex. 150, p. 1.)

B. Respondent's experts

1. Andrew MacGinnitie, M.D., Ph.D.

a. Qualifications

Dr. MacGinnitie received his B.A. in psychology from Yale University in 1987, and a Ph.D. in pathology in 1996 and a M.D. in 1998, both from the University of Chicago, Pritzker School of Medicine. (Ex. J, p. 1; Tr. 214-15.) He completed his residency in pediatrics in 2001, and his fellowship in allergy/immunology in 2004, both from the Children's Hospital in Boston. (*Id.*) From 2004 to 2011, Dr. MacGinnitie held concurrent clinical and faculty appointments at the University of Pittsburgh School of Medicine, serving as an Assistant Professor of Pediatrics and as an Attending Physician in Pediatrics and Allergy/Immunology at the University of Pittsburgh Medical Center. (*Id.*) Since 2011, he has held these same concurrent positions at the Harvard Medical School and the Children's Hospital Boston. (Ex. J, p. 1; Tr. 215-17.)

Dr. MacGinnitie also served as a consultant and as a member of the scientific advisory board for various pharmaceutical companies. (Ex. J, p. 2.) He is a reviewer for several medical journals, and an editorial board member of the *Annals of Allergy, Asthma and Immunology*, in addition to the *Journal of Allergy and Clinical Immunology: In Practice*. (*Id.*, p. 3; Tr. 218.) He has published numerous medical articles and book chapters in peer-reviewed journals, and has regularly given presentations within his area of specialty throughout his career. (Ex. J, pp. 5-14.)

Dr. MacGinnitie filed an expert report on December 21, 2015. (Ex. I.) He also testified at the evidentiary hearing held in Washington, D.C. on February 26, 2016. (Tr. 214-269.)

b. Summary of Dr. MacGinnitie's opinion

Dr. MacGinnitie was offered as an expert in allergy and immunology, and primarily offered a rebuttal to Dr. Mikovits' expert opinion in this case. Overall, Dr. MacGinnitie opined that there was "no evidence" that W.R. had an overactive immune system after any of his vaccinations, that he had an immune deficiency due to his vaccinations, or that any of his vaccinations caused any of W.R.'s ~~neurological disorders.~~ (Tr. 248; *see also* Ex. I, pp. 5-6.) Specifically, Dr. MacGinnitie opined that there was "no evidence" in W.R.'s contemporaneous medical records that he had an "abnormal level of inflammation or immune activation" (Ex. I, p. 5), and pointed to W.R.'s comprehensive testing of his immune system reflecting that W.R. had a *normal* immune system. (Tr. 233-38; *see also* Ex. I, pp. 3-4.)

First, Dr. MacGinnite offered an overview of W.R.'s condition in the early years of his life, opining that he did not consider W.R.'s routine ailments during that time period to be reflective of an abnormal immune system, and thus effectively rebutted a major factual predicate underlying Dr. Mikovits' opinion in this case. (Tr. 223-38; Ex. I, p. 5.) He specifically refuted Dr. Mikovits' classifications of W.R.'s symptoms around the time of his first set of vaccinations of November 19, 2008, opining that (1) he did not deem W.R.'s documented eczema at that time to be indicative of an "autoimmune disease" (Tr. 223); (2) that there was no evidence of W.R. having a bacterial infection at that time (*id.*); and (3) that Dr. Mikovits' opinion that W.R.'s green drainage at that time was indicative of a bacterial sinusitis had been "disproven" (*id.*). Moreover, Dr. MacGinnitie pointed to W.R.'s contemporaneous medical records that reflected that W.R.'s eczema seemed to be actually getting *better* by his doctor visit of August 20, 2009,

refuting Dr. Mikovits' assertions that W.R.'s "eczema" was exacerbated after his first set of vaccinations *and* his vaccinations thereafter. (Tr. 226; *compare* Ex. 19, p. 8.)

Finally, he opined that, at most, W.R.'s testing for food allergies was reflective of a possible egg allergy, but that there was no evidence that W.R. had allergies to multiple foods, as alleged by Petitioners in this case. (Ex. I, p. 6.) In this regard, he convincingly refuted another major factual predicate that was important to Drs. Mikovits' and Dr. Megson's opinions in this case; they alleged that W.R. had many food allergies in the early years of his life, thus indicating an abnormal immune system. Specifically, Dr. MacGinnitie disputed Drs. Mikovits' and Megson's heavy reliance on W.R.'s "patch testing" allergy results, purportedly indicating that W.R. had a "reaction" to 17 out of 20 foods that were tested, as support for their proposition that W.R. has many food allergies. (Tr. 239-41.) He pointed out that "patch testing" for potential food allergies was not approved by the FDA, and convincingly discussed how testing for food allergies is typically conducted -- typical testing that was not conducted in W.R.'s case. (*Id.*) In contrast, he argued that W.R.'s patch testing results, in fact, reflect the *opposite* of the main argument that Drs. Megson and Mikovits seemed to advance in this case, pointing out that *if* W.R. was in fact allergic to aluminum as claimed by Drs. Megson and Mikovits, then he would have reacted to *all 20 foods* on his "patch testing" due to the fact that the main apparatus used for "patch testing" was *comprised* of aluminum. (*Id.*)

2. Jeffrey Johnson, Ph.D.

a. Qualifications

Dr. Johnson received his B.S. in Biology in 1984 and a M.S. in Pharmacology in 1986, both from the University of Minnesota. (Ex. H, p. 2; Tr. 381.) He received his Ph.D. in Environmental Toxicology in 1992 from the University of Wisconsin, and completed his postdoctoral fellowship in the Department of Pharmacology at the University of Washington in 1995. (Ex. H, p. 1; Tr. 381.)

From 1995 to 1999, Dr. Johnson was an Assistant Professor within the Department of Pharmacology, Toxicology and Therapeutics at the University of Kansas Medical Center. (Ex. H, p. 1.) Since 1999, he has been at the University of Wisconsin-Madison School of Pharmacy, rising to become full Professor in 2007. (*Id.*) Dr. Johnson has published approximately 90 medical articles in peer-reviewed journals, authored several book chapters, and has regularly given presentations within his area of specialty. (*See* Ex. H.)

Dr. Johnson filed an expert report on September 28, 2015. (Ex. G.) He also testified at the evidentiary hearing held in Washington, D.C. on February 29, 2016. (Tr. 380-438.)

b. Summary of Dr. Johnson's opinion

Dr. Johnson systematically refuted Dr. Deth's opinion in this case, opining that there was "not sufficient scientific evidence" supporting Dr. Deth's proposed link between vaccinations and neurodevelopmental disorders, such as autism. (Tr. 417; *see* Ex. G *generally*.) Moreover, he opined that there was no evidence that W.R. suffered from "oxidative stress" as theorized by Dr. Deth, pointing out that, *if* W.R. in fact suffered from "oxidative stress," then his clinical symptoms would have been *far worse* than the symptoms W.R. currently exhibits. (Tr. 383.) Overall, Dr. Johnson, who also testified as one of Respondent's experts in the OAP "test cases"

discussed in Section II above, opined that, when laid bare, Dr. Deth was generally offering the *same theory* that Dr. Deth presented as an expert on behalf of the petitioners in the OAP "test cases" (Tr. 383) -- a theory that was thoroughly *rejected.*

Dr. Johnson questioned Dr. Deth's interpretations of the underlying facts used to support Dr. Deth's expert theory, providing specific citations to W.R.'s contemporaneous medical records to show that several of the statements made in Dr. Deth's expert report were greatly exaggerated. (Ex. G, p. 2.) Moreover, Dr. Johnson provided a detailed analysis of the medical literature used as support for Dr. Deth's expert opinion. (Tr. 385-411; Ex. G, pp. 4-14.) Overall, Dr. Johnson opined that the medical literature relied upon by Dr. Deth either: (1) did *not* support Dr. Deth's theory in this case; (2) flatly *contradicted* Dr. Deth's theory; or (3) were studies that were either subsequently discredited, or had such numerous and fundamental flaws that they there were, in essence, *thoroughly unreliable.* (*See* Tr. 388-410; Ex. G, pp. 2-4.)

In summary, Dr. Johnson concluded that Dr. Deth's opinion in this case, which, in essence, proposed ways that vaccinations might cause autism, was "fatally flawed." (Ex. G, p. 14.)

3. Edward Cetaruk, M.D.

a. Qualifications

Dr. Cetaruk received his B.S. in Biochemistry from the University of Massachusetts at Amherst in 1986, and earned his M.D. from New York University School of Medicine in 1991. (Ex. D, p. 2; Tr. 715.) In 1994, he completed his residency in emergency medicine from the University of Massachusetts Medical Center, and later completed his fellowship in Medical Toxicology from the Rocky Mountain Poison Center. (Ex. D, p. 2; Tr. 715.) In 1996, he completed a fellowship in Emergency Medicine Research at the University of Colorado Health Sciences Center. (*Id.*)

Dr. Cetaruk has been an Attending Faculty Member of the Rocky Mountain Poison and Drug Center Fellowship in Medical Toxicology since 1996, and an Assistant Clinical Professor of Medicine at the University of Colorado Health Sciences Center since 2000. (Ex. D, p. 1; Tr. 715-16.) Starting in 2002, he has also been an Adjunct Faculty Member at Louisiana State University's National Center for Biomedical Research and Training. (*Id.*; Tr. 718.) Dr. Cetaruk, has specialized in his career in *medical toxicology*, the study of the effect of potentially toxic substances on humans, and is board-certified in that specialty. (Ex. C, p. 2; Tr. 714, 722.) Dr. Cetaruk has also been an Emergency Medicine physician at several private hospitals throughout his career. (Ex. D, pp. 3-4; Tr. 718.)

He has published numerous medical articles in peer-reviewed journals, authored a book chapter, and has been invited to give several research presentations within his area of specialty. (Ex. D, pp. 7-15.) He has also served as a manuscript reviewer for the *Annals Of Emergency Medicine* and the *Journal of Toxicology - Clinical Toxicology.* (*Id.*, p. 5.)

Dr. Cetaruk filed an expert report on September 4, 2014 (Ex. C), and also testified at the evidentiary hearing held in Washington, D.C. on March 14, 2016. (Tr. 714-88.)

b. Summary of Dr. Cetaruk's opinion

Dr. Cetaruk was offered as an expert in the field of medical toxicology (Tr. 723), and primarily refuted the opinions of Drs. Shaw, Exley, and Palevsky (Tr. 727-41; *see also* Ex. C generally). Dr. Cetaruk opined that there was no scientifically reliable basis for Petitioners' theory in this case that the aluminum adjuvants in vaccinations were responsible for W.R.'s condition. (Tr. 740.) Similarly, he opined that there was "insufficient scientific evidence to provide a reliable scientific basis" for the theories advanced by Drs. Shaw, Exley, and Palevsky, that there is a certain "sensitive pediatric population" that, due to underlying genetic predispositions, "cannot detoxify and excrete aluminum," thus leading to accumulation of aluminum in brain tissue. (Ex. C, pp. 17-18.)

[OPINES W.R.'S AUTISM IS A SEQUELA OF HIS ENCEPHALAOPTHY AND DISTINGUISHES, ALSO OPINES ALUMINUM CONTAINING VACINES CAN CAUSE ENCEPHALAOPTHY – WHICH IS A POSSIBLE MECHANISM, NOT THE MEDICAL THEORY OF THE CASE]

Although Dr. Cetaruk agreed with a few points made by Drs. Shaw and Exley, primarily that aluminum had a long half-life (Tr. 733), and that a typical person would have traces of aluminum in brain tissue (*id.*), he vehemently disagreed with a primary premise of Drs. Shaw and Exley -- that there was no "safe level" of aluminum in the human body, since aluminum is classified as a neurotoxin (*id.*). He explained that dosage is "very, very important in toxicology" (Tr. 726), and that, as a general matter, aluminum "can be toxic," but that it is a "matter of dose and circumstance" (Tr. 734). He provided an example of the "botulinum toxin," which, according to Dr. Cetaruk, was the "most toxic compound known to man," yet is a substance that is routinely administered to humans in small doses for cosmetic purposes, primarily to reduce wrinkles. (Tr. 726.) Thus, he explained that the tiny amount of aluminum contained in vaccinations is *not* toxic (Tr. 727), and that there was no *reliable* medical literature stating that the amount of aluminum exposure from vaccinations can cause aluminum toxicity in patients (Tr. 728), or that the *cumulative amount* of aluminum in the typical childhood vaccination schedule would be toxic (*id.*).

Moreover, Dr. Cetaruk convincingly rebutted one of the primary studies[52] relied upon by Dr. Shaw to formulate his opinion in this case -- a study which purported to show that high levels of aluminum in patients undergoing dialysis treatment can cause a neurological condition termed as "dialysis associated encephalopathy" (DAE). (Tr. 133-135). He pointed out that in that study utilized by Dr. Shaw, patients on dialysis were exposed to levels of aluminum that were "astronomically high" (Tr. 734), and thus, that study was not applicable in this case, where W.R. received only the very tiny amounts of aluminum contained in vaccinations (*id*). Similarly, Dr.
Cetaruk disagreed with a major premise of Dr. Palevsky in this case -- that substances such as aluminum contained in vaccinations can easily cross the "blood-brain barrier" to cause
neurological harm. (Tr. 736.) In this regard, he refuted one of the primary studies relied upon by Dr. Palevsky, Ex. 319, pointing out several aspects of that study -- *e.g.*, the study was conducted in mice rather than humans, and had "quite high" doses of aluminum directly injected into the brain (Tr. 738) -- that made the results of that study inappropriate as a basis for support in this case. (Tr. 735-38.)

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[52] Dr. Shaw admitted at the evidentiary hearing that Petitioners had *not* submitted into the record of this case that particular study, which purportedly linked very high doses of aluminum to a condition called "dialysis associated encephalopathy" (DAE). (Tr. 134-35.)

4. Max Wiznitzer, M.D.

[DR. WIZNITER OPINES W.R.'S AUTISM IS LATER THAN HIS ENCEPAHLAOPTHY, AND THAT MOTOR TYPE ISSUES ARE ENCEPHALAOPTHY (not autism). HE ALSO STATES HE IS OPINING CONTRARY TO THE COURT WHEN HE OPINED ON ENCEPHALOAPTHY. THE SPECIAL MASTER MADE THAT OPINE THE FOUNDATION OF HIS, CONTRARY TO LEGAL DEFINITION OF ENCEPHALOAPTHY IN THE ACT AND SUPREME COURT PRECEDENT]

a. Qualifications

Dr. Wiznitzer earned his B.S. in Medicine in 1975 and his M.D. in 1977, both from Northwestern University School of Medicine. (Ex. B, p. 1; Tr. 789.) He completed his residency in pediatrics at the Children's Hospital Center in Cincinnati in 1980, and completed his fellowship in developmental disorders at the Cincinnati Center for Developmental Disorders in 1981. (*Id.*) Thereafter, he completed a fellowship in pediatric neurology at the Children's Hospital of Philadelphia in 1984. (*Id.*) In 1986, Dr. Wiznitzer completed his fellowship in Higher Cortical Functions at Yeshiva University, Albert Einstein College of Medicine. (Ex. B, pp. 1-2; Tr. 789-90.) Since 1986, Dr. Wiznitzer has been at Case Western Reserve University, where he has risen to concurrently serve as an Associate Professor of Pediatrics, Neurology, and International Health. (*Id.*) Dr. Wiznitzer received a National Research Service Award from the Albert Einstein College of Medicine in 1986, and was recognized as the Professional of the Year by the Autism Society of Ohio in 1991. (Ex. B, p. 3.) He was certified by the American Board of Pediatrics in 1982, the American Board of Psychiatry and Neurology with special qualification in Child Neurology in 1986, and the National Board of Medical Examiners in 1978. (*Id.*, p. 5; Tr. 790- 91.) Dr. Wiznitzer served on the editorial board of *Pediatric Neurology*, *Journal of Child Neurology*, and *Lancet Neurology*. (Ex. B, p. 6; Tr. 793.) He has co-authored 58 peer-reviewed articles, 4 book chapters, and 55 abstracts, and has authored 7 books. (Ex. B, pp. 13-23; Tr. 797.) He has also been invited to give hundreds of academic presentations throughout his career. (Ex. B, pp. 23-25; Tr. 796.) Dr. Wiznitzer filed an expert report on September 4, 2014. (Ex. A.) He also testified at the evidentiary hearing held in Washington, D.C. on March 14, 2016. (Tr. 789-889.)

Summary of Dr. Witnitzer's opinion

Dr. Wiznitzer refuted several of the expert opinions offered by the Petitioners in this case, with a primary emphasis on rebutting Dr. Megson's opinion. (*See* Ex. A and Tr. 789-890 *generally*.) Overall, Dr. Wiznitzer opined that there was no evidence in the contemporaneous medical records that W.R. had adverse reactions to any of his vaccinations (Tr. 846), and that
there was "no evidence" of a "developmental regression" following his 19-month DTaP, as claimed by Petitioners and their experts in this case (Tr. 847). Moreover, he opined that there was no evidence that any of W.R.'s vaccines caused or contributed to any of W.R.'s developmental disabilities [AND WAS NEVER A CLAIM OR ALLEGATION](Tr. 847; Ex. A, p. 24), further opining that W.R.'s "clinical course" was, in fact, "consistent with a developmental trajectory of ASD" (Ex. A, p. 24).

Dr. Wiznitzer offered a thorough analysis of W.R.'s contemporaneous medical records to systematically refute several of the major underlying factual predicates upon which Dr. Megson based her expert opinion (Tr. 803-13), and to opine that W.R.'s clinical presentation was typical for children with an autism spectrum disorder (Tr. 813-25). Notably, Dr. Wiznitzer discussed W.R.'s medical records from his first year of life, opining that, contrary to Dr. Megson's representations, W.R. showed delays in numerous developmental areas throughout that time

[DR. WIZNITER OPINES MOTOR ISSUES ARE ENCEPHALAOPTHY, NOT AUTISM, AND DOCUMENTS 12 MONTHS OF LOSS OF SKILLS, AND LOSS OF POINTING, BEFORE AND AFTER FROM MEDICAL RECORDS IN HIS REPORT, BUT DENIED REGRESSION ON THE STAND, CONTRARY TO THE MEDICLA RECORDS AND HIS REPORT, LIKE THE POST HEARING BRIEF FILED SHOWING EXACTLY WHERE HE CONCEEDS REGRESSION HE DENIES]

period (Tr. 800-02); and pointed to W.R.'s medical records at 18 months of age, opining that those records reflect that W.R. was "developmentally behind" in "all spheres" at that time (Tr. 803). Moreover, Dr. Wiznitzer strongly disagreed with Dr. Megson's opinion that W.R. experienced "significant developmental regression" after receiving the DTaP vaccination of May 4, 2010 (Tr. 805), refuting her opinion on this critical issue by providing numerous citations to W.R.'s contemporaneous medical records which reflected that, in essence, his developmental skills in numerous areas were the *same* before and after his DTaP vaccination of May 4, 2010 (*see* Tr. 805-13). [DR. WIZNITZER LEFT OUT THE SKILLS PRIOR IN HIS OPINE, AND REBUTTAL WITH HANDOUT SHOWING WHERE DOCUMENTS WHAT HE LEFT OUT. LIKEWISE, THE TRANSCRIPT SHOWS DR. MEGSON CITING THE RECORDS, PROOF IN TRANSCRIPT] [DR WIZNITZER ALSO IGNORED 5 YEARS OF NEUROLOGY RECORDS WHEN OPINING OF THE LETTER BELOW OUT OF CONTEXT, INCONSISTENT WITH THE VERIFIABLE MEDICAL RECORDS, SHOWING BOTH DIAGNOSES ON THE SAME VISIT, REGRESSION IN MEDICAL RECORDS].

Moreover, Dr. Wiznitzer discussed the statements made by Dr. Civitello, one of W.R.'s treating neurologists in this case, who provided a medical letter, Ex. 102, which indicated that W.R. experienced a regression contemporaneous to his vaccinations (*see* Ex. 102), effectively pointing out several flaws with that letter (Tr. 813-18). Similarly, Dr. Wiznitzer refuted certain aspects of the opinions of Drs. Ratajczak and Palevsky. In this regard, he opined that (1) Dr. Ratajczak's belief that the "blood-brain barrier" was not fully formed until the age of 36 months of age, was "totally incorrect" (Tr. 832-33); (2) that Dr. Palevsky's overall theory -- that the human brain developed in a pattern similar to that of the "reptilian brain" -- "goes against all the knowledge we have about brain development" (Tr. 837); and (3) that *none* of the references cited by Dr. Palevsky in his expert report supported Dr. Palevsky's theory that certain substances contained in vaccinations, such as "polysorbate 80," contributed to W.R.'s brain injury in any way (Tr. 845-46).

5. Bruce Cohen, M.D.

a. Qualifications

Dr. Cohen received his A.B. in Chemistry from Washington University in 1978, and his M.D. in 1982 from Yeshiva University, Albert Einstein College of Medicine. (Ex. F, p. 1.) He completed his residency in pediatrics in 1984 at the Children's Hospital in Philadelphia, and his residency in pediatric neurology in 1987 at Columbia Presbyterian Medical Center. (*Id.*) He also completed a fellowship in pediatric neuro-oncology in May 1989 at the Children's Hospital of Philadelphia. (*Id.*) From 1989 to 2011, Dr. Cohen was a Staff Physician at the Cleveland Clinic's Neurological Institute, serving as Chairman of Pediatric Neurology from 1999 to 2002. (*Id.*, p. 2.) From 1992 to 2003, he also concurrently served as an Associate Professor of Pediatrics at the Ohio State University Department of Pediatrics. (*Id.*) He has been a Professor of Pediatrics at Northeast Ohio Medical University since 2011. (*Id.*) Moreover, he is the current Director of Neurology and the Interim Director of the Neurodevelopmental Science Center at the Children's Hospital Medical Center of Akron, in addition to being a Staff Member at the Department of Neurology at Akron General Hospital. (*Id.*) Dr. Cohen has served as a reviewer and on editorial advisory boards of 11 scientific journals. (Ex. F, p. 3.) He has been invited to give over 600 presentations and lectures throughout his career. (*Id.*, pp. 5-33.) Additionally, he has co-authored 93 peer-reviewed scientific articles, 96 abstracts, and a textbook, and has authored 30 book chapters within his area of specialty. (*Id.*, pp. 36-48.)

Dr. Cohen's expert report was filed on September 28, 2015 (Ex. E), but he did not testify at the evidentiary hearing.

b. Summary of Dr. Cohen's opinion

Dr. Cohen's expert opinion in this case primarily rebutted the opinion of Petitioners' expert Dr. Suzanne Goh, and, like Dr. Goh, he did not testify at the evidentiary hearing in this case. (*See* Ex. E generally.) Dr. Cohen opined that W.R. did not have a "mitochondrial illness" or an "ongoing mitochondrial dysfunction" (*Id.*, p. 11), and that W.R.'s presentation of symptoms was "most consistent with the presentations of children with autism" (*Id.*). Moreover, he opined that there was "no evidence in the contemporaneous medical records of a regression following any vaccinations." (*Id.*)

[BECAUSE DR. WIZNITZER CONCEEDED REGRESSION IN HIS REPORT FROM CONTEMPORANEOUS MEDICAL RECORDS, AND BECAUSE THE MEDICAL RECORD SHOWS THE A LEADING MD REFERRED DID NOT RULE OUT MITOCHONDRIAL DYSFUNCTION AFTER CHROMOSOMAL TESTING, DR COHEN'S REPORT IS INCONSITENT WITH THE MEDICAL RECORDS IN COURT RECORD].

VI

SUMMARY OF MY OPINION

Unfortunately, it is not completely clear exactly what Petitioners are arguing in this case [DTAP FROM ENCEPHALAOPTHY WAS FOUND BY EXPERTS, WHY DTAP PRESCRIBING INFORMATION WAS FILED PRIOR TO HEARING]. For example, as will be detailed below, Petitioners and their experts were not even clear as to *what injuries* [MEDICAL OPINE STATES ENCEPHALOPTHY FROM DTAP] that W.R. purportedly suffered were allegedly caused by his vaccinations. From my careful review of this case, it seems to me that the Petitioners' counsel and their experts, in combination, purposefully relied upon a "kitchen sink" approach to this litigation, offering an ever-changing litany of suggestions of different mechanisms by which W.R.'s vaccinations might have harmed him, in the hopes that one suggestion might prove persuasive. Moreover, the scope of Petitioners' expert testimony seemed to shift throughout this litigation, confounding the issues as to (1) the *exact* condition in W.R alleged to have been vaccine- caused, and (2) the *precise explanations* as to *how* W.R.'s vaccinations allegedly caused those injuries. Petitioners' ten different experts put forward *many different* suggestion as to how W.R.'s many vaccinations during his first 20 months of life *might* have injured him. In many cases, those experts seemed to merely *suggest* possible causation theories, without any substantial explanation, much less support, for such theories. Thus, to specifically describe, discuss, and refute every one of the suggestions of Petitioners' experts would take an opinion hundreds of pages long. Nevertheless, I will, in this Decision discuss, and reject, the *chief theories* propounded by Petitioners' experts. And in this Section VI of my Decision, I will. I outline the issues to be discussed in this Decision, and my summary of that discussion.

[INCORRECT, 4TH DTAP CAUSING ENCEPHALOPATHY, AS CLEARLY FOUND BY THE MASTER IN THIS DECSION]

In this case, Petitioners seek a Program award, contending that W.R.'s neurological and alleged immunological injuries were "caused-in-fact" by the vaccinations administered to him in the first 20 months of his life. After thoroughly reviewing the record of this case, I have found *all* of the causation theories advanced in this case to be quite *unpersuasive.* There are many reasons to reject the Petitioners' overall theory that W.R.'s vaccinations caused his neurological deterioration and alleged immunological injuries, but I will highlight the most important here.[53]

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[53] Petitioners have the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

Petitioners' ten different experts put forward *many different* suggestion as to how W.R. many vaccinations during his first 20 months of life *might* have injured him. In many cases,

[FROM FACTS; "**Additionally, Mrs. Rogero's affidavits listed selective language from certain of W.R.'s medical records in order to describe W.R.'s condition before and after his DTaP vaccination of May 4, 2010;** she alleged, in essence, that W.R. was able to perform many tasks prior to his May 2010 vaccination that he subsequently lost after that vaccination.[38] (Ex. 276, p. 10, ¶¶ 47, 51.)..." ON Appx. 46a – SINCE HE LEAVES OUT THE CONTEMPRANEOUS MEDICAL RECORDS FROM THIS DECISION, AND THE EXPERTS ARE QUOTING THE SAME LANGUAGE AS THE MEDICAL RECORDS, THE BELOW OPINION IS CONTRARY TO THE EVIDENTIARY RECORDS] First, I note that Petitioners' experts in this case based their causation opinions not primarily upon the *medical records*, [INCORRECT ASSERTION AND VERIFIABLE IN TRANSCRIPT WITH EXHIBIT NUMBERS AND ACTUAL RECORDS] but most heavily upon *additional symptoms* allegedly displayed by W.R. during his early years of life, as set forth in the affidavits of the Petitioners, plus Mrs. Rogero's hearing testimony. Thus, in Section VII(A), I first rule as to whether the *additional* facts alleged by W.R.'s parents concerning W.R. -- *i.e.*, those facts that *do not* appear [FILED TO BOTH COURTS OF WHERE THEY DO APPEAR, INCONSITENT WITHTIS OPINION FROM THE CONTEMPORANEOUS MEDICAL RECORDS] in W.R.'s contemporaneous medical records -- are accurate descriptions of W.R.'s medical history. In this regard, I do *not* find, to be reliable, the written and oral testimony offered by W.R.'s parents, alleging that W.R. suffered *additional* post-vaccination symptoms after each set of vaccinations administered to W.R. in his early years of life, [THIS DECISION DOCUMENTS FROM MEDICAL RECORD THE POST VACCINATION ADVERSE EFFECTS, AGAIN CONFLICTING THE CONTEMPORANEOUS RECORD] symptoms that are *not reflected* in his contemporaneous medical records.[THE MASTER DOCUMENTS SKIN ISSUES, BRONCHIOLITIS, AND ENCEPHALOAPTHY FROM THE MEDICAL RECORD, MATCHING THE ADVERSE EFFECTS ON THE DTAP PRESCRIBING INFORMATION AND OPINED BY MD'S] In this regard, I emphasize that I am not questioning the sincerity or honesty of the Petitioners. I simply find the *contemporaneous medical records*, reflecting W.R.'s condition at the time his parents sought medical care during his early years of life, to be more reliable. [EXCEPT HE DID NOT USE THE MATERIAL FACTS FROM THOSE RECORDS]

Therefore, based on my rejection of the additional factual allegations made by the Petitioners, I necessarily find that Petitioners' experts relied on two critical *misassumptions of fact* in formulating their respective expert opinions. Thus, in Sections VII(B), (C), and (D). I discuss the critical incorrect assumptions of fact found in Petitioners' expert opinions that render their opinions, as a whole, to be *fatally flawed*, and thus *wholly unreliable*.
[THIS CONTRACDICTS FINDINGS OF FACTS THE MASTER WROTE "**Additionally, Mrs. Rogero's affidavits listed selective language from certain of W.R.'s medical records in order to describe W.R.'s condition before and after his DTaP vaccination of May 4, 2010; see Appx. 46a]**

A second crucial reason, as set forth in detail at Section VIII of this Decision, is that the *qualifications* of Respondent's experts were *overwhelmingly superior* to the extremely weak qualifications of Petitioners' experts. [THE ACT REQUIRES MEDICAL OPINE OR MEDICAL RECORDS NOT STRENGTH UNDER THE ACT]

A third reason is that a comparison of the expert reports and expert testimony in this case demonstrates that Respondent's experts were *far more persuasive* than Petitioners' experts. (*See* Sections IX of this Decision, below.) [PREPONDERNACE, NOT PERSUASIVENESS IS REQUIRED BY THE ACT, ERRONEOUS CONSTRUING OF SECTIONS 11 OF THE PROGRAM] A fourth reason is that Petitioners' experts failed to demonstrate the *basic premise* of their causation arguments, that the tiny amount of *aluminum* in vaccination *can* cause any harm

to vaccinees. They wholly failed to show that the aluminum in *W.R.'s own* vaccines caused him to suffer an "encephalopathy," caused his autism spectrum disorder, or caused any other harm. (See Section X, below.) [THE BASIC PREMISE IS DTAP CAUSES ENCPEHALAOPTHY, THE MASTER IDENTIFIED ALUMINUM IS A POSSIBLE MECHANISM ON APPX. 100A AND INCONSISTENT WITH THE VACCINE ACT TO REQUIRE A MECHANISM, UNDER ALTHEN] Another reason is that Petitioners' experts failed to demonstrate another part of their causation theory, that W.R. had an *immune system disorder*. (Section XI.) [THE CLEAR DIAGNOSES FROM HIS IMMUNOLOGIST STATES HE HAS AN IMMUNE PROBLEM] Another reason is that Petitioners' experts failed to demonstrate a different part of their causation theory, that W.R.'s *genetic variants* made him more susceptible to harm by vaccinations. (Section XII.) [THIS IS BE A LEGAL ERROR TO REQUIRE UNDER THE ACT FROM FEDERAL CIRCUIT PRECEDENTS]

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those experts seemed to merely *suggest* possible causation theories, without any substantial explanation, much less support, for such theories. Thus, to specifically describe, discuss, and rebut every one of the suggestions of Petitioners' experts would take an opinion hundreds of pages long. Nevertheless, I will in this Decision discuss, and reject, the chief theories propounded by Petitioners' experts. And in this Section VI of my Decision, I will.

Petitioners' experts also failed to demonstrate another part of some of those experts' theories, that W.R. had a *mitochondrial disorder* that allegedly made him more susceptible to injury by vaccination. (Section XIII.)

I also conclude that a letter by a treating physician, *Dr. Civitello*, did not support Petitioners' causation theory (Section XIV); that many of Petitioners' own experts acknowledged the very *speculative nature* of their own theories (Section XV); that the *medical* literature filed by Petitioners did not provide significant support to their causation theory (Section XVI); that *Mrs. Rogero's* testimony and filings were not persuasive (Section XVII); that Petitioners' argument that "this is not an autism case" was not persuasive (Section XVIII); and that Petitioners' case clearly failed to meet any elements of the *Althen* causation test (Section XX.) [THIS IS ERRONEOUS, THE DTAP PRESCRIBING INFORMATION LISTING ENCEPHLOPATHY WAS FILED IN 2013. ADDITIONALLY, THE ACT IS ON PREPONDERANCE STANDARD NOT AN ARBITRARY PERSUASIVE STANDARD OF A SPECIAL MASTER. MOREOVER, HE DID NOT USE DR. CIVETELLOS RECORDS THAT DOCUMENTS REGRESSION AFTER THE May 2010 DTaP]]

VII

PETITIONERS' EXPERTS RELIED ON THREE CRITICAL *MISASSUMPTIONS OF FACT* IN FORMULATING THEIR RESPECTIVE EXPERT OPINIONS

One crucial reason why I reject Petitioners' expert theories in this case is that their experts all relied on at least *three critical misassumptions of fact* that run *contrary* to the clinical history presented by the medical records. In this regard, three of Petitioners' experts -- Drs. Megson, Ratajczak, and Mikovits -- premised their expert opinions on the factual assumption that W.R. experienced developmental regression immediately or very soon after his *first set of vaccinations* at two months of age. Moreover, Drs. Megson, Palevsky, Goh, and Seneff also relied on a second factual assumption -- that W.R. suffered from developmental regression immediately or very soon after his *DTaP vaccination of May 4, 2010.* And, at least two of Petitioners' experts -- Drs. Mikovits and Megson -- assumed that W.R. experienced distinct regressions after *each of his first six* vaccine administrations.

Those three factual assumptions, however, are *not* supported by the factual record of this case. I address those assumptions below.

A. I credit the contemporaneous medical records over the contrary testimony of the Petitioners.

In adopting these three critical assumptions of fact, Petitioners' experts, to a great extent, were relying upon the affidavits submitted by the two Petitioners, Mr. and Mrs. Rogero (Exs. 40, 41, and 276) and the testimony during the evidentiary hearing of Mrs. Rogero (Tr. 479-611, 896-947). In those affidavits and testimony, the two Petitioners often described symptoms and behavior by W.R. that is *not* reflected in the contemporaneous medical records. After carefully listening to Mrs. Rogero's testimony and studying the affidavits, however, I conclude that in those instances where the Petitioners described symptoms and behavior *not* appearing in the contemporaneous medical records, I must credit the *contemporaneous medical records* over the assertions of the Petitioners. In this regard, I simply do not find, to be reliable,

the written and oral testimony offered by W.R.'s parents alleging that W.R. suffered additional post-vaccination symptoms after each set of vaccinations administered to W.R. in his early years of life--*i.e.*, alleged symptoms that are *not reflected* in his contemporaneous medical records. I emphasize that I am not questioning the *sincerity* or *honesty* of the Petitioners. I

simply find the contemporaneous *medical records*, reflecting W.R.'s condition at the time his parents sought medical care during his early months of life, to be more reliable.[54]

B. The overall record contradicts the assumption that W.R. suffered a "regression" shortly after his first set of vaccinations at two months of age.

First, the causation theories of several of Petitioners' experts were premised upon an assumption that W.R. experienced a significant regression in his development shortly after his *two-month vaccinations* on November 19, 2008. For example, Dr. Megson termed that alleged regression to be "most profound and immediately obvious." (Ex. 104, p. 9.) Similarly, Dr. Ratajczak stated that, after W.R.'s first set of vaccinations, W.R. had "tremendous developmental delay that set in," and that such developmental delay was "quite profound." (Tr. 633.) Also, Dr. Mikovits opined that W.R.'s "growth, GI health and dermatitis all showed immediate regression within weeks of the 2 month vaccinations." (Ex. 236, p. 13.) My analysis of the overall record, however, leads me to conclude that this assumption was *not* accurate.

After full consideration, I do *not* find that it is more likely than not that W.R. experienced symptoms of a neurological regression shortly following his vaccinations of November 19, 2008. Rather, I find that the medical records *contradict* the assumption of Petitioners' experts in this regard.

To summarize, W.R.'s medical records concerning the next several weeks after November 19, 2008, *do not* reflect W.R. having any neurologic regression at that time. (In this

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[54] The relevant case law states that medical records "warrant consideration as trustworthy evidence." *Cucuras v. HHS,* 993 F.2d 1525, 1528 (Fed. Cir. 1993). Accordingly, where subsequent testimony conflicts with contemporaneous medical records, special masters usually accord more weight to the medical records. *See, e.g., Reusser v. HHS,* 28 Fed. Cl. 516, 523 (Fed. Cl. 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.").

To be sure, "it must [also] be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." (*Murphy v. HHS*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992)). However, in balancing these considerations, special masters under the Vaccine Act have in most cases declined to credit later testimony over contemporaneous records. (*See, e.g., Stevens v. HHS*, No. 90-221V, 1990 WL 608693, at *3 (Cl. Ct. Spec. Mstr. Dec. 21, 1990); *see also Vergara v. HHS*, No. 08-882V, 2014 WL 2795491, at *4 (Fed. Cl. Spec. Mstr. May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony.") *See also Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (noting that "the Supreme Court counsels that oral testimony in conflict with contemporaneous documentary evidence deserves little weight").)

regard, I note that Petitioners' experts *all* failed to point to any *contemporaneous medical records* describing W.R.'s alleged regression after his two-month vaccinations.)

In fact, the next time the medical records reflect contact by W.R.'s parents with his physician was fourteen days later, on December 3, 2008. On that date, W.R. was seen by Dr. Dalton for eye drainage and rash. (Ex. 35, pp. 6-7.) At that time, his parents reported that W.R. had a white discharge and redness around his arms for one week, and that his cradle cap was "significantly better." (*Id.*, p. 6.) Upon examination, Dr. Dalton assessed that W.R. had seborrhea (discharge) around his eyelids, infantile eczema on his trunk and extremities, but that his cradle cap from his prior visit was "significantly improved." (*Id.*, pp. 6-7.) *There is no mention in that record of any developmental or neurologic regression by W.R.* **[AND NOT A CLAIM]**

Thereafter, forty-five days after his first set of vaccination, on January 3, 2009, W.R. was seen at Saint Francis Hospital for cough and congestion -- symptoms that his parents reported were ongoing for the past month. (Ex. 35, p. 8; Ex. 24, p. 8.) Two chest x-rays were performed but no abnormalities were found. (Ex. 24, p. 8.) *Again, no mention of any developmental or neurological regression is noted in the medical records* . **[AND NOT A CLAIM]** In short, there were only two medical record notations during the period between his vaccinations of December 3, 2008, and mid-January of 2009, yet neither of those records contain any indication whatsoever that W.R. suffered regression of any sort after his first vaccination set at two months of age. **[TRANSCRIPT STATES MEDICAL SKIN REGRESSION NOT NEUROLOGICAL]**

C. The overall record also contradicts the assumption that W.R. suffered from a "regression" soon after his DTaP vaccination in May of 2010.

Next, I note that several of Petitioners' experts in this case also relied on the factual assumption that W.R. suffered from "developmental regression" following his DTaP vaccination of May 4, 2010. **[DOCUMENTED IN MEDICAL RECORD OF PEDIATRICIAN AND NEUROLOGIST IN 2010]**

I begin by noting that Dr. Megson classified W.R.'s alleged developmental regression after his DTaP vaccination of May 4, 2010, as being "most profound" and "immediately obvious." (Ex. 104, p. 9.) But again, as noted in the subsection immediately above, Dr. Megson failed to point to any *contemporaneous* medical records that supported this factual assumption; instead, she indicated that this assumption was based on the *parents' later testimony*. (Ex. 104, p. 1, ¶ 1.) **[SHE OPINED IN TR. AND QUOTED DR. PANITZ, MD EXAM FINDINGS VERBATIM OF JUNE 8, SAME AS PARENTS WORDS AS FILED BY HHS]**

Dr. Palevsky also relied on an assumption that "[a]t 19 months, [W.R.] received his final vaccine, DTaP . . . [s]oon after that, he regressed, and lost speech." (Ex. 243, p. 4.) Similarly, Dr. Seneff assumed that "W.R.'s last vaccine was the DTaP administered at 19 months, and he experienced developmental regression following that vaccine." (Ex. 88, p. 2.) And Dr. Goh, too, accepted the assertion of Mrs. Rogero that, soon after the 19-month DTaP vaccination, W.R. had a regression of language and other skills. (Ex. 150, p. 2.) **[AND QUOTES MEDICAL RECORDS]**

My analysis of the overall record, however, leads me to conclude that this assumption was *not* accurate. As such, I do *not* find that it is more likely than not that W.R. experienced "the most profound" and "immediately obvious" regression shortly following his DTaP vaccination of May 4, 2010. Rather, I find that the contemporaneous medical records *contradict* that

assumption, as they *do not* reflect W.R. having any kind of regression soon after his DTaP vaccination.[55]

In my discussion below, I lay out W.R.'s numerous visits with his medical care providers in the time period shortly following his DTaP vaccination of May 4, 2010. I do so to highlight that Dr. Megson's factual assumption was *contrary* to W.R.'s contemporaneous medical records.

1. W.R.'s routine care/emergency department visits in the time period shortly after his DTaP vaccination of May 4, 2010

W.R's first visit with his treating pediatrician, after May 4, 2010, occurred only three days after his vaccination, on May 7, 2010. On that day, W.R. simply returned for a check of a "TB Test" (Ex. 5, p. 5), which proved on May 7 to be "negative" (*Id.*, p. 6). The record mentions no "regression" or any symptoms at all in W.R. at that time. (*Id.*, p. 6.) Thereafter, W.R. was seen again by his treating pediatrician on June 28 and 30, 2010, for an evaluation for rhinorrhea and constipation. (*Id.*, pp. 3-4.) Among other things, those records from his treating pediatrician reflect a description of W.R. as being a 21-month old boy with failure-to-thrive and autism. (*Id.*)

Next, on July 20, 2010, W.R. had an examination by a different pediatrician, for a chief complaint of "autism." (Ex. 33, p. 3.) That record reflects a medical history of W.R. given by Mrs. Rogero, reporting, among other things, that W.R. was "developmentally behind in all areas," was late to walk (reporting that he started to walk in May 2010), and that he had "no speech." (*Id.*) Moreover, that record also reflects Mrs. Rogero reporting, among other things, that she was concerned that W.R. had "mercury poisoning," and that she had "done much reading on [the] internet" about autism, investigating several possibilities as to the causes of W.R.'s then-present condition. (*Id.*) Overall, W.R.'s treating physician documented a plan to follow up with certain of W.R.'s medical care providers, recommending that Mrs. Rogero start W.R. on physical therapy ("PT"), occupational therapy ("OT"), and speech therapy ("ST"). (*Id.*, p. 2.)

W.R. also had two emergency department visits in the four months after his DTaP vaccination of May 4, 2010. On July 22, 2010, W.R. was admitted to the emergency department for complaints of erythematous plaques around his mouth, swelling of the lip and tongue, and wheezing. (Ex. 31, pp. 21-29.) At that time, he was assessed as having an allergic reaction. (*Id.*) Thereafter, W.R. was seen again by the emergency department on September 18, 2010, for complaints of cough and congestion, and was assessed with having an acute upper respiratory infection, not otherwise specified ("Acute URI NOS"). (*Id.*, p. 13.)

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[55] To be sure, the records from June through August of 2010 indicate clearly that W.R. was experiencing serious developmental delay, indicative of an autism spectrum disorder, during the period. But that developmental delay appears to have been a *continuation* of the developmental delay that had been noted in W.R. during his physician visits in 2009 and early 2010. It does *not* indicate a *regression* in W.R. during May to August of 2010.

2. Specialist evaluations in the time period soon after W.R.'s DTaP vaccination of May 4, 2010

Additionally, W.R. was evaluated by several specialists in the time period soon after his DTaP vaccination of May 4, 2010. I discuss those visits below.

a. Developmental pediatrician **[ALL RELEVANT ENCEPHALOPATHY EVIDENCE IS ABSENT THIS DECISION FROM EXAM – AFTER DTAP]**

On June 8 and 15, 2010, W.R. was twice evaluated by a developmental pediatrician. (Ex. 6, pp. 3-6.) During those visits, Dr. Panitz took W.R.'s medical history,[NOT EXAM] as reported by his parents, stating that W.R. "is able to babble,[HISTORY] but does not use language in any meaningful way,[EXAM]" "makes eye contact,[HISTORY] but doesn't always respond to being called or verbal requests,{EXAM]" and that he "does not point or use other gestures."**[EXAM, see April and before was pointing]** (*Id.*, p. 3.) At that time, W.R. was administered the"STAT" test (standardized test of autism for children two years of age), revealing that W.R. was "well above the threshold for 'at risk' for autism." (*Id.*, p. 5.) On language and cognitive testing,
W.R. was assessed as having "severely delayed" language skills, but was assessed as having normal cognitive skills. (*Id.*) Overall, Dr. Panitz assessed W.R. as having "receptive and expressive language skills" that are "significantly delayed," and as having significant delays within his non-verbal communicative intents. (*Id.*) Dr. Panitz overall assessed W.R. as follows:

> [W.R.] engages in repetative (*sic*) and restricted behaviors and meets the DSM [Diagnostic and Statistical Manual] criteria for Autism. Due to his young age, we will defer the assignment of this diagnostic label until after his 2nd birthday, even though the literature indicates that the presence of these significant findings is likely to be consistent.

(Ex. 6, p. 5.)

[ABSENT ALL RELEVANT MEDICAL RECORD FROM MAY_JULY HERE]

Approximately eleven weeks after his DTaP vaccination, on July 22, 2010, W.R.'s medical records reflect a notation of a phone call between W.R.'s developmental pediatrician and Mrs. Rogero. (Ex. 6, p. 64.) At that time, Mrs. Rogero provided a description of W.R.'s condition at that time, during which, among other things, Mrs. Rogero stated that W.R. was "much more interactive" at that time, and that he was "looking for attention." (*Id.*)

b. Neurological consultations and testing

W.R. also underwent several neurological consultations in the time period soon after his DTaP vaccination of May 4, 2010.

Approximately fifteen weeks after his DTaP vaccination, on August 18, 2010, W.R. was evaluated by a neurologist. (Ex. 28, pp. 13-15.) That neurologist's consultation notes reflect the following:

> Mom describes [W.R.] to occasionally seem to have unresponsive episodes and would like him to be evaluated for possible seizures, something she has read may be present in autism.

(Ex. 28, p. 13.) Overall, that neurologist assessed W.R. as having an "autistic disorder current or active state," and with having "other convulsions." (*Id.*, p. 14.) In that medical record, W.R.'s treating neurologist also further elaborated upon her assessment of "other convulsions," noting that, although those episodes did "not seem significant," she was ordering a routine EEG to "obtain a baseline study evaluation in children with autism." (Ex. 28, p. 14.)[56]

c. Developmental therapy sessions

I also note that W.R. had numerous developmental therapy sessions in the time period soon after his DTaP vaccination of May 4, 2010. Those records show his developmental therapists working with W.R. to meet various developmental target goals. (*E.g.,* Ex. 34, pp. 10-12, 17-19, 25-32, 39, 41-42, 51-53.)

3. Summary of W.R.'s contemporaneous medical records in the period shortly after his DTaP vaccination of May 4, 2010

In short, there are numerous medical record notations during the four-month period of May through August of 2010, yet none of them contain *any indication whatsoever* that W.R. suffered from a developmental regression, much less any evidence of a regression that was "profound" or "immediately obvious," as assumed by Dr. Megson. In this regard, I highlight that the parents did not report to their treating physicians that there was any regression in W.R. during that time period.

Thus, the contemporaneous medical records show no signs whatsoever of a key fact that Dr. Megson assumed -- *i.e.*, "profound" and "immediately obvious" developmental regression soon after the DTaP vaccination of May 4, 2010.[57]

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[56] As I noted in Section IV above, W.R.'s EEG study conducted on October 25, 2010, yielded normal results and showed no seizure activity. (Ex. 9, p. 144.)

[57] In this regard, I am mindful that a number of medical records, created months or years *after* the DTaP vaccination of May 4, 2010, indicate that W.R.'s parents *later* reported that the onset of certain symptoms in W.R., such as an alleged developmental regression, occurred following his DTaP vaccination. (*E.g.*, Ex. 9, pp. 154-57; and a number of other medical records all created on or after September 29, 2010.) But those later records do not indicate *how soon* after the DTaP vaccination in question the described symptoms occurred. More importantly, I rely more heavily on the medical records created starting in *May 2010 through August 2010,* as detailed above, rather than records created thereafter. Upon my close examination of the overall record in this case, I heavily rely on the records created during this time period, for several reasons.

First, the overall record of this case appears to show that, after W.R.'s treating physicians suspected W.R. of having an autism diagnosis sometime in June 2010 (*e.g.*, Ex. 5, pp. 3-4; Ex. 6, pp. 3-6), W.R.'s parents started consulting various treatment care providers, sharing their views on the potential causes or treatments for autism (*e.g.*, Ex. 33, pp. 2-3 (reflecting correspondence between two of W.R.'s treatment care providers revealing that Mrs. Rogero inquired about

Further, my conclusion on this issue, that Petitioners' experts were *erroneous* in their assumption that W.R. suffered from a "profound" and "immediately obvious" regression shortly after his DTaP vaccination of May 4, 2010, is *not* changed by my careful consideration of the affidavits and hearing testimony of W.R.'s parents. In this regard, I credit the contemporaneous medical records as the more reliable evidence.

D. The medical records also contradict the factual assumption that W.R. suffered distinct regressions after <u>each</u> of his first six vaccine administrations.

Some of Petitioners' experts at times stated, and based their opinions on, the assumption that W.R. supposedly suffered distinct regressions after *each* of his first six vaccine administrations. For example, Dr. Mikovits assumed a regression "following each [vaccine] dose." (Ex. 236, p. 12.) And, Dr. Megson stated that "each vaccination" caused a spike in multiple conditions in W.R., including "encephalopathy." (Ex. 104, p. 9.)

But this third factual assumption, of distinct regressions after each of W.R.'s first six vaccine administrations, was clearly yet another *erroneous assumption.* First, I have already explained above, in parts B and C of this Section VII, why I conclude that there was *no regression* after (1) W.R.'s *first* set of vaccinations, on November 19, 2008, or (2) his *sixth* vaccine administration, the DTaP vaccination on May 4, 2010. And, after closely examining the

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testing for "mercury poisoning" and potential changes in W.R.'s diet that might help "cure" W.R.'s autism); Ex. 28, p. 13 (Mrs. Rogero requesting W.R.'s neurologist to evaluate W.R. for possible seizures, as she had read that seizures "may be present in autism")).

Second, the overall record of this case also reflects that, starting in March of 2011, Mrs. Rogero actively solicited several of W.R.'s treating physicians to either (1) testify on behalf of the Petitioners in this case (*e.g.*, Ex. 26, p. 21 (Mrs. Rogero asking W.R.'s nutritionists to be open to testifying in this case and being a "voice for children such as my son in vaccine court"); Ex. 245, p. 23 (W.R.'s records of his visit with Dr. Megson on March 11, 2014, documenting that W.R. was "referred by Cliff Shoemaker" -- Petitioners' counsel in this case -- "for evaluation")); or (2) *revise* certain of their assessments in their contemporaneously-created consultation notes from their evaluation of W.R. in anticipation of those records being submitted in this present litigation (*e.g.*, Ex. 52, pp. 39-40 (Mrs. Rogero asking one of W.R.'s gastroenterologists to correct "several discrepancies"); Ex. 52, pp. 6-12 (Mrs. Rogero requesting W.R.'s treating geneticist to make "amendments" to his clinical consultation report concerning W.R.'s visit of April 12, 2012).

Third, the overall record of this case also reflects notations by W.R.'s treating pediatrician, who recorded that Mrs. Rogero was "convinced" that W.R.'s "developmental issues are secondary to vaccines," and that she was developing "her own treatment plan." (Ex. 42, p. 12.)

Thus, taken as a whole, I find W.R.'s treatment records created *close in time* to his DTaP vaccination of May 4, 2010, to be more reliable, than later records, on the issue of whether W.R. suffered a serious regression soon after that DTaP vaccination.

medical records following *each* of W.R.'s second, third, fourth, and fifth vaccine administrations, again I find *no evidence* of a distinct regression after any of those vaccine administrations. Instead, as Dr. Wiznitzer concluded, the medical records show that W.R.'s development *gradually* got further and further behind the typical child's developmental course, *without* a series of *distinct regressions* after each vaccine administration, as some of Petitioners' experts assumed. (*E.g.*, Tr. 800, 802-05, 806-11, 811-13). In other words, W.R.'s developmental history is *typical* for an ASD, not indicative of any sudden brain injury.

E. Summary: Petitioners' experts' incorrect assumptions

In sum, the most obvious reason to reject Petitioners' causation claim in this case is that their experts provided their causation opinions in this case based upon three *distinctly flawed assumptions.*

In this regard, three of Petitioners' experts -- Drs. Megson, Ratajczak, and Mikovits -- premised their expert opinions on the factual assumption that W.R. experienced developmental regression soon after his *first set of vaccinations* at two months of age. For the reasons discussed above, I conclude that this assumption was factually *incorrect.*

Second, Drs. Megson, Palevsky, Goh, and Seneff also relied on an additional factual assumption -- that W.R. suffered from a serious developmental regression soon after his *DTaP vaccination of May 4, 2010.* For the reasons discussed above, I conclude that this assumption was also factually incorrect.

And, finally, Drs. Mikovits and Megson also relied on a third factual assumption -- that W.R. experienced distinct developmental regressions *after each of his six* vaccine administrations. Again, I found this factual assumption to be factually incorrect as well.

Thus, because Petitioners' experts based their causation opinions chiefly upon *three flawed factual assumptions*, Petitioners have clearly *failed* to prove their causation case.[58] Therefore, I could reasonably end my analysis at this point. However, in the interest of completeness, in the pages to follow I will explain several other reasons for rejecting Petitioners' causation claim in this case.

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[58] "[T]o the extent that it relies on the testimony of the petitioners' witnesses as to the occurrence and timing of events, [expert medical opinion] must stand or fall with the fact testimony." (*Murphy v. HHS*, 90-882V, 1991 WL 74931, at *3 (Fed. Cl. Spec. Mstr. April 25, 1991), *aff'd,* 23 Cl. Ct. 726 (1991), *aff'd,* 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied*, 506 U.S. 974 (1992).) Thus, because I decline to credit Petitioners' testimony with regards to W.R.'s alleged developmental regressions, I likewise decline to accept the Petitioners' expert opinions based upon on that testimony.

VIII

RESPONDENT'S EXPERTS WERE *FAR* MORE QUALIFIED THAN PETITIONERS' EXPERTS

Another very strong reason why I must deny Petitioners' claim is that I found Respondent's experts to be *vastly* better qualified than the experts upon whom Petitioners relied. Four of the five Respondent's experts that testified in this case--Max Wiznitzer, Andrew MacGinnitie, Edward Cetaruk, and Gerald Raymond--are all medical doctors with outstanding credentials in their fields of expertise, each of whom has worked at renowned medical centers for many years. Each of them has expertise directly related to the causation theory advanced by Petitioners.

In contrast, Petitioners' experts that testified in this case are *far* less qualified, and/or suffer from serious credibility problems. In the sub-sections that follow, I will discuss the lack of qualifications of each of Petitioners' experts, in comparison to the qualifications of Respondent's experts.

A. Comparison of experts' qualifications

1. Mary Megson, M.D. (for Petitioners) vs. Max Wiznitzer, M.D. (for Respondent)

a. Neurodevelopmental disorders

Dr. Megson is a board-certified pediatrician who served for several years as a Clinical Professor of Pediatrics at the Medical College of Virginia, before launching her own pediatric practice. (Ex. 105, p. 1.) In her practice, to her credit, she has also treated a great many children with neurodevelopmental disorders, such as ASDs. *Long v. HHS*, No. 08-792, 2015 WL 1011740, at *7 (Fed. Cl. Spec. Mstr. Feb. 9, 2015). In contrast, however, Dr. Wiznitzer, Respondent's expert primarily rebutting Dr. Megson's testimony, is a *pediatric neurologist*, and thus has far superior *academic credentials* and *specialized medical training* in the area of *neurologic* and *neurodevelopmental disorders*, which is W.R.'s main area of disorder. The qualifications of Dr. Wiznitzer concerning diagnoses of encephalopathy, autism spectrum disorders, neurotoxicity, or neurodevelopmental disorders in general, are, thus, much superior to those of Dr. Megson in those subject matter areas.

In particular, Dr. Wiznitzer is far better qualified than Dr. Megson to opine concerning persons, like W.R., with *ASDs,* since Dr. Wiznitzer has devoted much of his career to *specializing* in autism. At the Rainbow Babies and Children's Hospital in Cleveland, Dr. Wiznitzer served as Co-Director of the Rainbow Autism Center in 1991, and as the Director of the Rainbow Autism Center from 1992 through 2010. (Ex. B, p. 3.) Clinically, he has treated and diagnosed thousands of patients with autism spectrum disorders for over 30 years, starting his intensive clinical experience during his fellowship at the Albert Einstein College of Medicine in Bronx, New York, a hospital that treated a large autism population. (Tr. 794-96.) Of Dr. Wiznitzer's extensive published medical articles, medical text chapters, and medical abstracts, a great many concern autism. (*See* Ex. B, pp. 15-16, 18, 20, 22; *see also* Tr. 797.) He has presented numerous lectures at the invitation of community organizations concerning childhood developmental disorders, primarily on the subject of autism. (*See* Ex. B, pp. 24-55; *see also* Tr.

796.) He has been extensively engaged in autism-related research throughout his career (Tr. 794-795), receiving funding from the National Institutes of Health for his research (Tr. 795; Ex. B, pp. 4-5). He is a member of the International Society of Autism Research. (Tr. 793.)

Dr. Megson's *curriculum vitae* and testimony, on the other hand, show no similar training specialization in or academic expertise in the specific field of autism. Therefore, Dr. Wiznitzer's qualifications to opine concerning causation *in a child with autism* are much superior.

Although Dr. Megson regularly treats children with developmental disabilities, including autism, she is not board-certified in any pediatric subspecialty. She is not a neurologist, nor does she have any specialized training concerning autism, nor any significant medical research or academic credentials. In contrast, Dr. Wiznitzer's has the extremely extensive background in pediatric neurology in general, and autism in particular, described above.

b. Qualifications to opine concerning other medical specialties

I additionally note that Dr. Megson also provided testimony in this case concerning various medical disciplines outside her specialty of general pediatrics, for which she was *thoroughly unqualified.* Dr. Megson is not board-certified in most of the disciplines as to which she testified in this case, such as neurology, toxicology, immunology, genetics, dermatology, or gastroenterology. (Tr. 63; *see also* Ex. 105.)

2. Judy Mikovits, Ph.D. (for Petitioners), vs. Andrew MacGinnitie, M.D. (for Respondent)

As noted above, Dr. Mikovits has qualifications as a researcher in biochemistry and molecular biology. Based on those credentials, her opinions regarding chemistry and molecular biology might deserve a certain amount of deference -- but only her opinions in those subjects. The scope of her expert testimony in this case, however, went *far beyond* those subjects, and veered into providing opinions on medical disciplines in which she was *wholly unqualified.* (*E.g.*, Tr. 958-59; Ex. 236, pp. 12-13.) At the start of the evidentiary hearing, Dr. Mikovits even admitted on direct examination that she was an expert "as to nothing" (Tr. 163), and that she was *not* a clinician that could testify on the many medical specialties relevant to this case (Tr. 204). But Dr. Mikovits' position regarding her own areas of expertise drastically shifted towards the end of the litigation, when she stated, quite unbelievably, that she was testifying on rebuttal to rebut "all" of Respondent's experts in this case, and claimed that she had "an expertise in every area" of the case in order to provide such rebuttal testimony. (Tr. 974.)

In contrast, Dr. MacGinnitie, Respondent's expert who primarily rebutted Dr. Mikovits' testimony, was far more qualified, as a medical doctor, to provide an opinion regarding the causation of *medical disorders* in W.R., as well as to opine concerning the topics of allergy and immunology. Dr. MacGinnitie currently holds concurrent positions at the Harvard Medical School and the Children's Hospital Boston. (Ex. J, p. 1; Tr. 215-17.) He is board-certified in both pediatrics and allergy/immunology, and currently serves as a clinical director for a division at the Children's Hospital Boston -- a position that exposes him to the medical specialties of dermatology and rheumatology, in addition to his experience in allergy and immunology. (Tr. 215-16.) Approximately 90 to 95 percent of his practice is devoted to caring for children with

allergic or immunologic disorders. (Tr. 216.) In this capacity, he consults with approximately 200 to 250 patients per year suffering from eczema, and consults with approximately 400 to 500 patients per year suffering from food allergies. (Tr. 217.)

Dr. MacGinnitie has also served as a reviewer for several medical journals, and as an editorial board member of the *Annals of Allergy, Asthma and Immunology*, in addition to the *Journal of Allergy and Clinical Immunology: In Practice*. (Ex. J, p. 3; Tr. 218.) He has published numerous medical articles and book chapters in peer-reviewed journals, and has regularly given presentations within his area of specialty throughout his career. (Ex. J, pp. 5-14.)

Thus, Dr. MacGinnitie has *far superior* qualifications, including his extensive training, publishing, and teaching as a medical doctor in the areas of allergy and immunology, than those of Dr. Mikovits, who extensively opined in those areas, without proper qualifications or expertise to do so.

3. Helen Ratajczak, Ph.D. (for Petitioners) vs. Dr. Wiznitzer (for Respondent)

Similar to Dr. Mikovits, Dr. Ratajczak has qualifications as a Ph.D. researcher -- in Dr. Ratajczak's case, in molecular biology and autism. Based on those credentials, her opinions regarding molecular biology and aspects of autism might deserve a certain amount of deference -- but only her opinions in those subjects. The scope of her expert testimony went *far beyond* those broad subjects, however, and attempted to offer clinical *medical opinions* regarding W.R.'s condition in the early years of his life. (*E.g.*, Ex. 216, pp. 4-5; Tr. 633-35.) In this regard, Dr. Ratajczak admitted that she is not a medical doctor, has not diagnosed patients, and has had no formal training in recognizing developmental delays. (Tr. 638-39.)

Thus, I find that Dr. Wiznitzer, Respondent's expert who primarily refuted Dr. Ratajczak's opinion regarding W.R.'s clinical condition in the early years of life, is far more qualified to provide an opinion on those issues than Dr. Ratajczak. As described above, Dr. Wiznitzer is a well-qualified *medical doctor* specializing in pediatric neurology, and has the requisite qualifications to provide such an opinion in this case.

4. Lawrence Palevsky, M.D. (for Petitioners) vs. Dr. Wiznitzer and Edward Cetaruk, M.D. (for Respondent)

To his credit, Dr. Palevsky is a medical doctor, was a board-certified pediatrician until December 2011 (Ex. 244, p. 3), and has a *curriculum vitae* reflecting that he served in various clinical positions at several pediatric hospitals in the greater New York City area (*id.*, p. 1). Thus, Dr. Palevsky does possess the *basic qualifications* necessary to credibly opine on medical issues regarding W.R.'s developmental trajectory. However, his *curriculum vitae* and testimony indicated that since 2002, the primary focus of his medical practice has been in serving as a pediatrician and consultant in a "holistic health" pediatric practice. (Ex. 244, p. 1; Tr. 445.) In other words, Dr. Palevsky's area of focus and experience since 2002 has *not* primarily been within a traditional pediatric practice setting. Moreover, he admitted at the evidentiary hearing that his current practice is a "consultation practice predominantly," and he does not have hospital privileges to be able to practice traditional clinical medicine at a hospital. (Tr. 474, 477.) Moreover, although

his *curriculum vitae* indicates that he has given several lectures on "holistic medicine" and on the safety and efficacy of vaccines (Ex. 244, pp. 3-5), he admitted at the evidentiary hearing that he does *not* conduct clinical research in his current professional capacity (*see* Tr. 474-77).

In contrast, Respondent's experts rebutting his opinion in this case -- Drs. Wiznitzer and Cetaruk -- have *far superior* qualifications and relevant experience practicing *traditional clinical medicine*, in order to effectively rebut Dr. Palevsky's testimony regarding the medical specialties of neurology and toxicology.

First, my extensive discussion concerning Dr. Wiznitzer's qualifications in subsections V(B)(4)(a) and VIII (A)(1)(a) above, is also applicable here for purposes of comparing Dr. Wiznitzer's qualifications with those of Dr. Palevsky. I specifically highlight that, while Dr. Palevsky was a board-certified pediatrician in a conventional clinical setting for a period of time, Dr. Wiznitzer has *subspecialties* in pediatric neurology and neurodevelopmental disabilities, and has specialized in *autism*, thus making him much more qualified, to opine concerning the causation of W.R.'s disorder in this case.

Second, Dr. Palevsky's qualifications regarding *toxicology*[59] -- a field in which he extensively provided an expert opinion in this case -- are *not* comparable to those of Respondent's expert, Dr. Cetaruk. Dr. Cetaruk is a medical doctor who has specialized in the study of *medical toxicology*, and is board-certified in that field. As a medical toxicologist, Dr. Cetaruk specializes in analyzing the *medical effect* on humans of potentially poisonous substances. (Ex. D, p. 1; Tr. 714.) Dr. Cetaruk is one of only 300 to 400 board-certified medical toxicologists in North America (Tr. 721), and only one of about 300 of those medical toxicologists who actively consults with patients in that capacity. Dr. Cetaruk has been an Attending Faculty Member of the Rocky Mountain Poison and Drug Center Fellowship in Medical Toxicology since 1996, and an Assistant Clinical Professor of Medicine at the University of Colorado Health Sciences Center since 2000. (Ex. D, p. 1; Tr. 715-16.) In that capacity, he has often diagnosed and treated patients with exposure to many harmful substances. When I compare Dr. Cetaruk's specialized training and experience regarding the *medical effects* of aluminum and other harmful substances on humans, I find that his opinion on that subject carries far more persuasive weight than that of Dr. Palevsky.

5. Christopher Shaw, Ph.D. (for Petitioners) vs. Dr. Cetaruk (for Respondent)

Similar to Drs. Mikovits and Ratajczak, Dr. Shaw, who possesses a Ph.D. in neurobiology, has general qualifications to opine in the subject area of neurobiology. (Ex. 87, p. 1; Tr. 94.) Like Drs. Mikovits and Ratajczak, Dr. Shaw provided expert testimony in areas that went *far beyond* his subject of expertise, and similarly to those two experts, attempted to provide

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[59] Toxicology is "the sum of what is known regarding poisons; the scientific study of poisons, their actions, their detection, and the treatment of the conditions produced by them." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012), p. 1942. *Medical toxicology* deals specifically with the cause, diagnosis, and treatment of *human* disease associated with exposure to any potentially toxic agent. (Ex. C, p. 2.)

a *medical opinion* concerning the potential for aluminum to cause ASDs in human infants (Ex. 86, pp. 2-3) -- an undertaking he was *wholly unqualified* for.[60]

In contrast, I find Respondent's expert Dr. Cetaruk, who primarily rebutted the expert opinion of Dr. Shaw in this case, to have *far superior* qualifications, as detailed above. Specifically, Dr. Cetaruk's extensive training, publishing, and teaching in the areas of *medical toxicology*, are far superior to those of Dr. Shaw, for the purpose of opinions regarding the alleged harmful effects of aluminum on humans.

6. Christopher Exley, Ph.D. (for Petitioners) vs. Dr. Cetaruk (for Respondent)

Dr. Exley possesses a Ph.D. in "Ecotoxicology of Aluminum," and certainly has qualifications to opine on the subject area of aluminum toxicity. (Ex. 87, p. 1; Tr. 94.) However, when compared with Respondent's expert Dr. Cetaruk, who offered the main rebuttal to Dr. Exley's opinion in this case, Dr. Exley's qualifications are not equal. Although Dr. Exley has authored several books and articles concerning the potential harmful effects of aluminum, he still is not a *medical* toxicologist. As discussed above, Dr. Cetaruk is a *medical toxicologist*, whose extensive training and clinical practice focuses on *treating patients* with high exposure to harmful substances, such as aluminum. Thus, while I credit Dr. Exley's extensive research experience in the field of aluminum, I find Dr. Cetaruk's qualifications, as a medical toxicologist, to be superior to those of Dr. Exley.

7. Richard Deth, Ph.D. (for Petitioners) vs. Jeffrey Johnson, Ph.D, and Drs. Cetaruk, MacGinnitie, and Wiznitzer

Dr. Deth has a Ph.D. in pharmacology, and has held faculty positions as a Professor at several universities. (Ex. 224, p. 1; Tr. 277.) Thus, he has the requisite qualifications to opine as to pharmacology.

However, Respondent's expert Dr. Johnson, who primarily rebutted Dr. Deth's testimony in this case, holds a Ph.D. in Environmental Toxicology, and has also held faculty positions as a professor at several universities. (Ex. H, p. 1.) Thus, with his credentials in *toxicology* he has qualifications superior to those of Dr. Deth in the specific subject of this case, *i.e.*, the potential *toxic* effects of aluminum. Moreover, Dr. Johnson testified that his research specifically focuses on "oxidative stress" and "neurodegenerative diseases." (Tr. 382-83.) Thus, his knowledge and experience concerning the *specific topics* of Dr. Deth's general causation opinion in this case -- that of "oxidative stress" and "neurodegenerative diseases" -- is superior to that of Dr. Deth.

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[60] Also, I found that Dr. Shaw's theory seemed to shift throughout this litigation, and that his testimony seemed to be purposefully evasive when pressed to articulate the *precise* scope of his theory. For instance, although his expert report and testimony alluded to W.R. possibly having an autoimmune disorder, known as "autoimmune/inflammatory syndrome induced by adjuvants" (ASIA) (Tr. 106; Ex. 86, p. 2), when questioned during cross-examination, he could *not* provide a clear answer as to an important aspect of his theory – whether he believed that W.R. even had an autoimmune disorder (Tr. 138-39).

Moreover, I note that Dr. Deth's expert reports and testimony contained numerous statements in which he seemingly attempted to provide a clinical and diagnostic opinion in this case. (*E.g.*, Ex. 242, p. 22.) I find that Dr. Deth is *wholly unqualified* to opine on those issues, and his qualifications regarding those topics are *far inferior* to the medical doctors that testified on behalf of the Respondent in this case, namely Drs. MacGinnitie, Wiznitzer, and Cetaruk.

8. Stephanie Seneff, Ph.D. (for Petitioners)

Even though Petitioners' expert, Dr. Seneff, did not testify at the evidentiary hearing, I point out some fatal flaws in her qualifications to opine as to any aspect of the causation opinion in this case. In this regard, I find that Dr. Seneff, whose *curriculum vitae* reflects that she has an undergraduate degree in biophysics, and a Ph.D. in electrical engineering and computer science (Ex. 89, p. 1), is *wholly unqualified* to provide an opinion concerning *any* of the scientific and medical causation issues in this case. In other words, although Dr. Seneff boldly offered an opinion regarding the many scientific and medical causation issues in this case, she lacked the basic qualifications to do so. (*See* Ex. 88, pp. 1-6.)

B. Certain of Petitioners' experts have questionable professional backgrounds.

I additionally note that several of Petitioners' experts have questionable professional backgrounds. For instance, Dr. Shaw acknowledged at the evidentiary hearing that one of his publications has been harshly criticized by the World Health Organization (WHO), the agency of the United Nations whose primary focus is on international public health issues. (Tr. 122.) Similarly, Dr. Mikovits admitted on cross-examination that one of her research papers was severely criticized and subjected to retraction from a scientific journal. (Tr. 205; *see also* Respondent's Trial Exhibit B.) Moreover, Dr. Mikovits even admitted that she was fired from her previous employment at the Whittemore Peterson Institute (Tr. 210), although she alleged that she was fired for exposing improper activities at that institute (*id.*).

Thus, the record of this case reflects that at least two of Petitioners' experts in this case have significant questions about their professional backgrounds.

C. Summary concerning qualifications of experts

In sum, for the reasons pointed out in detail above, in comparing the relative qualifications and reliability of the experts that testified in this case, I note that Respondent's experts are *far more* qualified than those of Petitioners' experts. Moreover, as also pointed out in detail above, there are severe problems with the Petitioners' experts' qualifications to offer opinions either that aluminum *can* contribute to the causation of neurodevelopmental disorders and/or autoimmune illnesses in general, or that aluminum-containing vaccinations *did* contribute to causing or aggravating the neurodevelopmental disorder and alleged autoimmune illness of W.R. himself.

In contrast, the collective qualifications of Respondent's four experts who testified at the evidentiary hearing in this case, to opine concerning the issue of whether aluminum can contribute to the causation of neurodevelopmental disorders and/or autoimmune illnesses in general, and whether W.R.'s vaccinations contributed to causing or aggravating W.R.'s own neurodevelopmental disorders and autoimmune illnesses, are *vastly superior* to the qualifications

of Petitioners' experts. That is another major reason why I must rule against Petitioners in this case.

IX

RESPONDENT'S EXPERT REPORTS WERE *FAR* MORE *PERSUASIVE* THAN PETITIONERS' EXPERT REPORTS

A. Comparison of the persuasiveness of the expert opinions in this case

As explained in the previous Section VIII of this Decision, Respondent's experts in this case are vastly more *qualified* than Petitioners' experts. And another reason for denying Petitioners' claim is that Respondent's expert reports and testimony were also *much more persuasive* than those of Petitioners' experts. As I have already explained in Section VII of this Decision above, most of Petitioners' experts who provided opinions specific to W.R.'s case relied upon *incorrect* assumptions concerning W.R.'s medical history. Those six experts -- Drs. Mikovits, Ratajczak, Seneff, Megson, Palevsky, and Goh -- were completely unpersuasive for that reason alone. In my discussion below, I discuss a few of the many *other* shortcomings of the Petitioners' expert opinions, leading me to conclude that overall, the Petitioners' expert opinions offered in this case were completely *unpersuasive*.

1. The record of this case revealed evidence of bias of the Petitioners' experts

First, I find that the record of this case revealed reasons to conclude that most of the opinions provided on behalf of the Petitioners in this case, if not all of them, were tainted with a *pre-existing bias* in these experts to find a causal relationship between vaccines and developmental disorders, especially autism.

For example, as mentioned in footnote [ ] above, the record from W.R.'s first visit with Dr. Megson, in March of 2014, reflects a notation by Dr. Megson documenting that W.R. was referred to her for evaluation by Petitioners' counsel, Attorney Shoemaker. (Ex. 245, p. 23.) Thus, Dr. Megson should not be considered an ordinary "treating physician" of W.R., whom W.R.'s parents merely happened to consult in the ordinary course of their search for medical help for W.R. Instead, it is clear that Dr. Megson is a physician who many years ago, for whatever reasons, concluded that vaccines can be a cause of autism or autism-like symptoms in children. Over the years, Dr. Megson has testified that *many different* types of vaccines, and vaccine ingredients, can cause or aggravate ASDs. For example, in one case Dr. Megson testified that the *influenza vaccination* significantly aggravated a child's "pre-existing neurologic problems, including his autism, making them far worse." *Long v. HHS*, No. 08-792V, 2015 WL 1011740, at *8 (Fed. Cl. Spec. Mstr. Feb. 9, 2015). Similarly, in another ASD case, *Hooker v. HHS*, No. 02-472V, 2016 WL 3456435 (Fed. Cl. May 19, 2016), Dr. Megson testified that the "exposure to *mercury*" from that child's "thimerosal-containing vaccines" (*id.* at *14, emphasis added) caused the child's autism. And in yet another case involving a child with an ASD, Dr. Megson testified that the child experienced a vaccine-induced encephalopathy caused by *DTaP* and *MMR* vaccines, resulting in his ASD symptoms. *Murphy v. HHS*, No. 05-1063V, 2016 WL 3034047 (Fed. Cl. Spec. Mstr. April 25, 2016).

Now, in this case, she takes yet *another approach*, opining that the *aluminum adjuvant* in vaccinations can cause an "encephalopathy" resulting in autistic symptoms.

Moreover, in my extensive studies concerning the alleged causal relationship between vaccines and autism for the past 15 years (see Section II above), I have come to understand that there is a small group of physicians and non-physician medical researchers, including Dr. Megson and Dr. Deth, who, for whatever reasons, have come to embrace the idea that vaccines may play a role in the causation of autism, or what they often describe as "autistic-like symptoms." I have carefully studied the expert reports and hearing testimony of these medical experts, in dozens of Vaccine Act cases over the past dozen years, and uniformly found that their opinions, when weighed against the many relevant epidemiological studies, autopsy studies, other scientific studies, medical literature, and testimony of dozens of highly-credential "mainstream" experts in the field of autism and neurodevelopmental disorders, simply seem *contrary to the overwhelming medical/scientific evidence against them*. And several, if not all, of the petitioners' experts *in this case* seem to come from this small group of medical doctors or medical researchers who have embraced this "alternative theory" concerning the causation of autism.

For example, in addition to Dr. Megson, Dr. Shaw admitted that the majority of the articles that he cited in his expert report and testimony, which question a causal relationship between aluminum adjuvants and ASDs, are supported by organizations that question the safety of certain vaccines. (Tr. 143-44.) Moreover, Drs. Shaw, Exley, Deth, and Seneff are on the Scientific Advisory Board[61] of the Children's Medical Safety Research Institute ("CMSRI"), an organization that, as Respondent's post-hearing brief pointed out, has an agenda that is highly skeptical of vaccine safety. (*See* Respondent's Trial Exhibit 1, pp. 1-2; *see also* Tr. 696, 699.)

Thus, for the reasons discussed above, I find Petitioners' expert opinions, particularly those of Drs. Megson, Mikovits, Exley, Shaw, Deth, and Seneff, to be far less credible and persuasive, as they appear to be strongly biased, based upon *very* dubious evidence, toward the view that vaccines can cause autism or autism-like symptoms.[62]

2. Several of Petitioners' experts used dubious tactics while providing their expert opinion in this case.

Second, I note that several of Petitioners' experts in this case relied on dubious tactics while providing an opinion in this case -- tactics which gave me another reason to find those experts' opinions to be *far less* credible and persuasive. I highlight below the dubious tactics employed by three of the Petitioners' experts in this case, namely those of Drs. Palevsky, Mikovits, and Deth.

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61 Dr. Exley himself admitted that that Board is actually a "spurious scientific board" (Tr. 696), whose real purpose seems to be finding "research" that is critical of vaccines (Tr. 696-99).

62 I hasten to add that, despite my perception of this "bias" in Petitioners' experts, I have nevertheless studied their reports and testimony *carefully* in this case. I simply found very little merit in their scientific arguments, and found that their arguments were *strongly outweighed* by the arguments of Respondent's experts in this case.

a. Dr. Palevsky

I begin my discussion with Dr. Palevsky, who relied on a wholly discrediting tactic of citing to certain medical literature in his expert report that, after a close examination, actually did *not* support the proposition that he represented that medical literature as supporting.

For instance, Dr. Palevsky's expert report cited to a medical article, Ex. 319 (*Sharma et. al.*), to imply that that literature supports his opinion that "nanoparticles can induce brain edema formation by influencing the blood brain barrier breakdown." (Ex. 243, p. 7, citing to Ex. 319.) Instead of submitting the full article as an exhibit in this case, however, Dr. Palevsky only provided an *abstract* (very brief summary) of that article, thus making it impossible to fully understand that article. And, Dr. Wiznitzer pointed out at the evidentiary hearing, that, upon his own examination of the *entirety* of that article, he discovered several shortcomings of that article when compared to what Dr. Palevsky stated about that article. Specifically, Dr. Wiznitzer pointed out that the study 1) was performed on animals; 2) used a very different mode of exposure than what is derived from vaccines -- that is, the animals were *directly injected into the brain* with aluminum and several *other* substances concurrently; and 3) the dosage of the aluminum injected in the experimental animals was "*100-fold greater*" than the aluminum contained in vaccines. (Tr. 840-41.)

Moreover, Dr. Wiznitzer pointed out that the study referenced in Ex. 319 also showed that when "polysorbate 80" -- a substance in some vaccines that Dr. Palevsky opined could cause brain damage -- was administered by *itself*, there was no resultant "brain or spinal cord pathology whatsoever." (Tr. 841.) In other words, when the researchers of that study injected polysorbate 80 by itself into animal brains, those animal brains did *not* show signs of brain damage, thus offering *no support* to Dr. Palevsky's theory that substances like polysorbate 80 can cross the "blood-brain barrier" in *humans*, much less cause brain damage. Thus, as aptly described by Dr. Wiznitzer, Dr. Palevsky's reference to Ex. 319 was "useless" when used to support Dr. Palevsky's theory in this case. (Tr. 841.)

As another example, Dr. Palevsky cited in his expert report to an article examining the effects of aluminum in rabbit brains (Ex. 314 -- *Bombi et. al.*), as support for his proposition that polysorbate 80 and aluminum could cause brain damage via inflammation of the brain. (Ex. 243, p. 6; *see also* Ex. 314.) Dr. Wiznitzer once again pointed out, however, that the actual article indicated that the authors of that study did *not* find any lesions in the rabbit brains (*see* Ex. 314, pp. 4-6, tables 2-4), thus flatly undermining Dr. Palevsky's representations to the contrary (Tr. 842-43).

b. Dr. Mikovits

Dr. Mikovits, like Dr. Palevsky, also cited in her expert report to an article that vastly overstated the support for the point that Dr. Mikovits attempted to make. In this regard, Dr. Mikovits cited in her expert report to a study -- the "Louveau *et. al.*" study (Ex. 239) -- for the proposition that toxic substances can cross *into* the brain, touting that study as being a "discovery which changes our knowledge and understanding" of this area of science (Ex. 236, p. 10 of 19). Dr. MacGinnitie pointed out, however, that that study (1) was predominantly conducted in mice and only examined *nine* human tissue samples as a comparison point; (2) was a study that showed that when blue dye was injected directly into the brain of experimental mice, that blue

dye could be transported *out of* the brain, but did not show that substances could flow *into* the brain. (Tr. 246-48.) In other words, the Louveau study, referenced by Dr. Mikovits, did *not* show that toxic substances can flow *into* the brain, but merely showed that substances could flow *out of* the brain when injected directly into the brain. Thus, as summarized by Dr. MacGinnitie, the Louveau study that Dr. Mikovits touted as being an instrumental premise of her opinion in this case, in fact *did not* support the point that Dr. Mikovits attempted to make. (*Id.*)

c. Dr. Deth

As an effective rebuttal of Dr. Deth, Dr. Johnson pointed out several fatal flaws of the studies cited in Dr. Deth's expert report and testimony as support for his theory in this case. (Tr. 392-416.) As one reflective example, I highlight the *Muratore* et. al. study -- a study that Dr. Deth co-authored and cited in his expert report and in his presentation slides at the evidentiary hearing. (*See* Petitioners' Trial Exhibit D, slide 24 of 77.) Dr. Johnson pointed out that the study was *not* submitted with the expert report of Dr. Deth (Tr. 394), and Dr. Johnson himself introduced that article as Respondent's Trial Exhibit E (Tr. 418). Moreover, Dr. Johnson discussed at length the internal inconsistencies with that article (Tr. 394-99), noting, in essence, that the particular data from that paper, upon which Dr. Deth relied, was "completely invalidated" by other representations made in that article (Tr. 397).

In a similar fashion, Dr. Johnson systematically pointed out fatal flaws in several other articles in which Dr. Deth was listed as a co-author, describing fundamental methodological flaws that made the results of those studies wholly unreliable. (Tr. 392-416.) As a reflective sample, Dr. Johnson pointed to one particular study that even lacked a control group, thus rendering the results of that study to be completely devoid of even the most basic scientific rigor. (Tr. 400.)

Thus, for all the reasons stated above, I find that three of the Petitioners' experts that testified in this case employed dubious tactics in providing an expert opinion in this case. For that reason alone, I find the opinions of Drs. Palevsky, Mikovits, and Deth, to be far less than persuasive.

3. There were several general problems with Petitioners' expert causation opinions in this case

In general, the *common theme* of all of Petitioners' expert opinions is that the *aluminum* used as an adjuvant[63] in vaccines can damage the brain of an infant, causing neurodevelopmental disorders, such as "encephalopathy" and autism spectrum disorders. However, the Petitioners' expert opinions fall far short of making a persuasive case that the tiny amount of aluminum-adjuvant contained in a single vaccine, or in the *entire series* of aluminum-containing vaccines that an infant receives, can have any such effect.

While the Petitioners' experts stated the *conclusion* that aluminum-containing vaccines can cause or aggravate neurodevelopmental disorders, such as an "encephalopathy" and ASD, those opinions were quite deficient in explaining *why* that might be so. Meanwhile, the opinions

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63 Dr. Cetaruk, a medical toxicologist, defined an adjuvant as "an additive to a vaccination that will enhance the immune response to the antigen of that vaccination to improve the likelihood that it will produce effective immunity for the patient." (Tr. 726-27.)

of Respondent's experts in this case explained persuasively that there simply is no scientific evidence supporting the theory that the amount of aluminum contained in vaccines can cause a neurodevelopmental disorder such as autism, or an encephalopathy, or affect the infant brain in any way.

In addition, I note that Petitioners' entire approach to their causation claim has been disjointed and inconsistent. That is, while certain of Petitioners' experts offering a *specific* causation opinion in this case -- mainly Drs. Megson and Mikovits -- allege that W.R. has an "encephalopathy" that is *distinct* from autism, certain of Petitioners' experts offering a *general* causation opinion in this case -- Drs. Shaw, Ratajczak, and Deth -- base their opinions on studies that purportedly show support for the *general* theory that vaccines can cause *autism*.

Further, those Petitioners' experts that expressed an opinion *specifically* concerning *W.R.* were *quite inconsistent* with one another. For example, as described above (Section VII) some of Petitioners' experts opined that W.R. was injured by his *first* set of vaccinations, some pointed to his *sixth* vaccine administration in May of 2010, while some pointed to *all six* of his vaccine administrations.

In short, in general I found the Petitioners' expert opinions to be *completely* unpersuasive, while the Respondent's expert reports were quite persuasive.

4. Other ways in which Petitioners' experts proved to be unpersuasive witnesses.

Finally, I note that, overall, I simply did *not* find Petitioners' experts to be solid, thoughtful, or persuasive witnesses. As noted in multiple instances above and below, Petitioners' experts often overstated the significance of the materials upon which they were relied, or outright misrepresented the materials upon which they based their expert opinions. This was true of both their analysis of the medical literature they cited, as well as their analysis of W.R.'s own medical records. Petitioners' experts also sometimes contradicted each other, or simply changed their testimony.

In contrast, Respondent's experts were far more measured, thoughtful, and credible as witnesses, and were vastly better able to *coherently explain* their opinions.

It is also noteworthy that despite advancing theories steeped in immunology and toxicology, *none* of the Petitioners' experts that testified in this case were either immunologists or medical toxicologists. Similarly, despite the fact that all of the Petitioners' experts also advanced a theory steeped in neurology, *none* of the Petitioners' *testifying* experts is a neurologist (*i.e.*, a medical doctor specializing in neurology). This fact makes the Petitioners' experts' overstatements in these fields all the more unpersuasive, because they do not have the proper academic, clinical, or research background to support their testimony.

B. Summary of Section IX

In short, after reviewing all of the expert opinions in this case, along with the accompanying medical literature, I conclude that the Respondent's experts, as a whole, were far more *credible* and more *persuasive* witnesses in this case. *See, e.g., Hennessey v. HHS*, No. 01-190V, 2009 WL 1709053, *42 (Fed. Cl. Spec. Mstr. May 29, 2009) ("When experts disagree, many factors influence a fact-finder to accept some testimony and reject other contrary

testimony. Objective factors, including the qualifications, training, and experience of the expert witnesses and the extent to which their proffered opinions are supported by reliable medical research, other testimony, and the factual basis for their opinions, are all significant in determining what testimony to credit and what to reject.").

X

PETITONERS' EXPERTS' FAILED TO DEMONSTRATE IN GENERAL THAT THE ALUMINUM CONTAINED IN VACCINES CAN RESULT IN AUTOIMMUNITY CAUSING NEURODEVELOPMENTAL DISORDERS, SUCH AS ENCEPHALOPATHY OR AUTISM

As noted above, Petitioners' overall theory in this case was that the aluminum in vaccines can cause a chronic autoimmune attack on the brain, resulting in neurodevelopmental disorders, such as encephalopathy or autistic symptoms. This general proposition, however, turned out to be poorly supported, quite speculative, and not persuasive.

On the other hand, I find that Respondent's experts' explanations rebutting the Petitioners' experts' general causation testimony, concerning the alleged effects of aluminum, to be highly persuasive. I discuss my main reasons for that conclusion below.

I begin by noting that Drs. Shaw and Exley's theories of aluminum leading to an autoimmune encephalopathy and other neurodevelopmental disorders were quite speculative. In this regard, Dr. Shaw even admitted that several of the medical articles that he extensively discussed at his evidentiary hearing testimony, were, at base, merely articles that provided a basis for "further hypothesis generation and experimental study." (Tr. 121.) For instance, Dr. Shaw acknowledged that one of the medical articles he extensively discussed at the evidentiary hearing -- Ex. 290 -- was a "perspective article" that attempted to provide a perspective on the "potential impact" of aluminum on the immune and nervous systems. (Tr. 104-05.) Moreover, he also acknowledged that another medical article he extensively discussed at the evidentiary hearing -- Ex. 284 -- was based on an "ecological study" (Tr. 108), a type of study that he admitted at a later point in his testimony served the limited purpose of serving as a *hypothesis-generating* device for *further research* (Tr. 120-21). In this regard, he also acknowledged that the World Health Organization (W.H.O.)'s criticism of one of his studies -- Ex. 253 -- was partly correct, stating that the W.H.O.'s criticism about ecological data not being as good as other kinds of data was "true in a very purest sense that [case-control studies] are considered to be superior [to ecological studies] for a variety of reasons because ecological data sets cannot be interrogated further." (Tr. 121-22.)

Similarly, Dr. Exley's explanation regarding several critical points of his general causation theory was very incoherent, including regarding (1) the potential ways that aluminum could infiltrate the body (Tr. 655-57); (2) how the aluminum in the body might infiltrate the brain (Tr. 667-75); or even whether aluminum in the body triggers an immune response (Tr. 686-89).

Thus, in closely examining the testimony of the Petitioners' experts opining as to the link between aluminum, autoimmunity, and neurodevelopmental disorders, I *do not* find them to be persuasive. Petitioners simply wholly failed to demonstrate that the tiny amount of aluminum brought into the body by vaccine adjuvants can cause any harm.

In contrast, Respondent's experts in this area were *highly persuasive*. Dr. Cetaruk explained that the concept of *dose* -- or the *amount* of a particular substance that a patient is exposed to -- is "very, very important in toxicology." (Tr. 726.) He gave the example of the botulinum toxin, a toxin he described as "[h]ands-down the most toxic compound known to man" (*id.*), which, if given in the right dose, is used for cosmetic purposes in humans to "take away wrinkles with no adverse effects" (*id.*). Thus, he opined that "dose really determines the difference" between something that is deemed to be a "medicine," and something that is deemed to be a "toxin" or "poison." (*Id.*)

Dr. Cetaruk explained that aluminum has been used as an adjuvant in vaccines since the 1920s, and that the amount of aluminum given to a patient through vaccinations has not been found to be toxic. (Tr. 727-28.) He explained that a typical patient receives approximately several hundred micrograms of aluminum from the administration of *multiple* vaccinations at one time, and opined that he was "not aware of any literature" finding that tiny amount of aluminum to "cause aluminum toxicity in those patients." (Tr. 728.)

Similarly, Dr. Cetaruk opined that there was no "scientifically reliable basis" for Petitioners' experts' general causation theory that the *cumulative amount* of aluminum in the typical childhood vaccine schedule would be toxic. (*Id.*) In this regard, he convincingly explained what happens to aluminum when it enters the human body, stating that the injected aluminum gets distributed throughout the body away from the site of where it was injected, with some of the aluminum being metabolized, or even excreted from the human body. (Tr. 730.)

Dr. Cetaruk strongly disagreed with the opinions of Drs. Shaw and Exley that there was no "safe level" of aluminum. (Tr. 733-34). Dr. Cetaruk pointed out that, in fact, most humans have some amount of aluminum in their brains (Tr. 733), but most of those people have "no evidence of neurotoxicity whatsoever." He explained that toxicity of aluminum in the human brain is a "matter of dose and circumstance" (Tr. 734), with low doses of aluminum being tolerated without any pathological effects, whereas pathological effects could potentially be seen in much higher doses (*id.*).

Moreover, Dr. Cetaruk opined that there was no scientifically reliable evidence that associated aluminum exposure with *autism* (Tr. 734-35), effectively refuting Petitioners' experts' reliance on ecological studies to opine to the contrary in this case (Tr. 740-41). In this regard, he convincingly explained that ecological studies are mainly useful as a comparison tool to show "two things occurring in a population" (Tr. 741), but that they "do not do anything to show causation between the two" (*id.*), and thus, cannot be used to establish a causation opinion in this case, as the Petitioners' experts attempted to do (Tr. 740-41).

In a similar fashion, Dr. Wiznitzer -- as the most credentialed expert in the specific study of *autism* in this case -- also opined that he was not aware of any reputable studies that concluded that aluminum can either cause, or exacerbate, an ASD. (Tr. 827.)

XI

THERE IS NO EVIDENCE OF ANY ABNORMAL IMMUNE REACTION OR ANY AUTOIMMUNITY IN W.R.

Even if the Petitioners' experts had demonstrated *in general* that the aluminum contained in vaccines *can* result in autoimmunity causing neurodevelopmental disorders, such as an "encephalopathy" or autism, they still failed to show that such an occurrence caused the *specific* encephalopathy or autism symptoms of *W.R.* Since Drs. Mikovits and Megson theorized that W.R.'s injuries are explained as an autoimmune "encephalopathy," manifesting as autistic symptoms that are secondary to that encephalopathy (Ex. 104, p. 7; Ex. 236, p. 18; Tr. 165-66, 188-89, 199, 204), their opinions in this case were, in essence, predicated on the idea that W.R. himself had an immune dysfunction and/or an abnormal immune reaction to his vaccinations in question. However, W.R.'s own medical history does *not* establish that any such abnormality or reaction existed in W.R., and the testimony of Respondent's experts *persuasively refutes* Petitioners' theory.

A. There was no evidence that W.R. had a compromised immune system prior to his first set of vaccinations, or any time thereafter.

One critical premise in Dr. Mikovits' theory was that at the time of W.R.'s first set of vaccinations on November 19, 2008, W.R. already had a severely-challenged immune system, leading to further damage to his immune system by W.R.'s vaccinations administered on that date. (Tr. 165-66; Ex. 236, pp. 11-12.) In this regard, Dr. Mikovits pointed to W.R.'s symptoms on November 19, such as his "cough," "congestion," "green nasal discharge," and "bad cradle cap," and opined them to collectively be indicative of a "strong" and "significant" immune response." (Tr. 165-66.) She opined that because W.R.'s immature immune system was already burdened by an autoimmune response on November 19, 2008, his young immune system became overwhelmed by the many "antigens" contained in the vaccinations that were administered to him at that time, thus triggering a "cytokine storm" leading to his alleged severe autoimmune reaction. (E.g., Tr. 165-67, 174-79; Ex. 236, pp. 11-12.)

Dr. MacGinnitie, as the only board-certified immunologist and allergist in this case, flatly rejected Dr. Mikovits' opinion on this issue. Instead, he opined that there was no evidence in W.R.'s contemporaneous medical records that he had an abnormal immune system before his first set of vaccinations, soon after those vaccinations, or any time thereafter.

Dr. MacGinnitie systematically went through W.R.'s contemporaneous medical records from November and December of 2008, opining that W.R.'s symptoms of "cradle cap,"[64]

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[64] Dr. MacGinnitie defined "cradle cap" as a "dermatitis of the scalp." (Tr. 222.) Moreover, he classified cradle cap as being similar to eczema, with the distinction being that cradle cap "affects the areas that are covered by hair on the scalp," whereas eczema is throughout the rest of

eczema, and green nasal drainage were *not* reflective of an autoimmune disorder. (Tr. 222-24.) In this regard, he rejected Dr. Mikovits' opinion that eczema is an autoimmune disease, testifying that the "overwhelming mainstream of thought" regarding eczema was that it was a "combination of a defect in the skin barrier and an inflammatory disease of the skin" and was "*not* related to autoinflammation." (Tr. 223, emphasis added.) Similarly, he rejected Dr. Mikovits' classification of W.R.'s green nasal drainage as indicative of "bacterial sinusitis," a theory which has been "disproven" in the medical community. (Tr. 223.)

Moreover, Dr. MacGinnitie asserted that *even assuming* that the aluminum adjuvants in a vaccination could in theory cause a reaction in a person, *W.R.'s case did not fit the appropriate timing* for such a reaction to have occurred. (Tr. 224.) Dr. MacGinnitie stated that if W.R. had experienced a reaction to his vaccinations of November 19, 2008, he would expect W.R. to have had noticeable symptoms *within 24 hours* of his vaccinations, especially a worsening of the rash that W.R. had at that time. (*Id.*) But the records do not show symptoms within 24 hours. Dr. MacGinnitie acknowledged that at W.R.'s *next visit* with his treating pediatrician, on December 3, 2008, W.R.'s eczema had worsened. But Dr. MacGinnitie explained that there is no known understanding for why infants develop eczema, and that eczema "waxes and wanes" for *many* reasons, including the simple fact that eczema is worse in the winter months than in the fall. (Tr. 225.) In other words, Dr. MacGinnitie articulated that, in his clinical experience, W.R.'s eczema in December of 2008 was a *common occurrence* in many of the infants he sees, and was *not* an immune reaction to his first set of vaccinations.

B. There was no evidence that W.R. had ongoing inflammation

Dr. MacGinnitie also flatly rejected the opinions of Drs. Megson and Mikovits had W.R. had ongoing "inflammation" throughout his early years of life. In contrast, Dr. MacGinnitie opined that there was "no evidence of systemic inflammation" in W.R. (Tr. 231.) He pointed to numerous testing of W.R.'s immune system throughout his contemporaneous medical records (Tr. 229-38), stating that comprehensive checks of W.R.'s immune system had been conducted throughout his life, and that all his results have been within normal limits (Tr. 238).

C. Summary

In sum, there is no significant evidence in the record to suggest that W.R. had an abnormal immune system, or suffered from autoimmune encephalopathy as Drs. Mikovits and Megson suggested. I found that the testimony of Petitioners' experts, to the effect that there existed an immune system abnormality in W.R., to be strongly outweighed by the contrary testimony of the better-qualified Dr. MacGinnitie. Similarly, Drs. Megson and Mikovits have presented *no* persuasive evidence that W.R. suffered from ongoing inflammation due to the cumulative effects of his vaccinations in the early years of life, and their testimony was *effectively refuted* by Dr. MacGinnitie in this respect as well. Thus, even if I were to accept the validity of Petitioners' theory that autoimmunity could cause neurodevelopmental disorders,

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the body. (*Id.*) He also stated that for reasons that are unknown in the medical community, young infants that have severe cradle cap are at high risk for developing more significant cradle cap at a later time. (Tr. 222.)

such as an encephalopathy or autistic symptoms, there is no persuasive evidence that such a phenomenon could explain *W.R.*'s own encephalopathy or autism.

XII

I FOUND NO MERIT IN THE PETITIONERS' THEORY THAT W.R.'S GENETIC VARIANTS MADE HIM MORE SUSCEPTIBLE TO HARM THROUGH VACCINATIONS

The majority of Petitioners' experts in this case -- namely, Drs. Megson, Shaw, Mikovits, Deth, Ratajczak, and Seneff -- seemed to opine that, due to certain genetic variants in W.R., he was especially susceptible to harm from the aluminum contained in his vaccinations.

I first note that the Petitioners' entire approach to this part of their causation claim was very disjointed and inconsistent. On this issue, the above-mentioned Petitioners' experts had disjointed theories as to (1) the *specific genetic variants* that made W.R. more susceptible to harm from his vaccinations, (2) the *type of injuries* caused by his genetic variants, and (3) *how exactly* those genetic variants made W.R. more susceptible to harm from his vaccinations.

For instance, Dr. Megson pointed to the fact that W.R. has a variant in *two* of his genes -- a "CCL_2 heterozygous gene variant" (Ex. 104, p. 7) (hereafter the "CCL2 variant") and a homozygous "SNP in the MTHFR enzyme at c677T" (Tr. 40) (hereafter the "MTHFR variant") -- opining that those variants rendered him "unable to detoxify" the aluminum adjuvants contained in his vaccinations, leading to W.R.'s "developmental regression" and "encephalopathy." (Ex. 104, p. 10; Tr. 55.) Similarly to Dr. Megson, Dr. Mikovits also pointed to the "CCL2" and the "MTHFR" genetic variants as making W.R. more susceptible to harm from his vaccinations (Tr. 950-52); however, she provided very muddled testimony as to *how* those variants within W.R. caused him to be more susceptible to harm from the aluminum in his vaccinations (*id.*). For example, Dr. Mikovits pointed to one particular study -- Rai *et. al.* (Ex. 327, Petitioners' Trial Exhibit G) -- for the proposition that the study showed "significant association between the c6772 polymorphism ["MTHFR" variant] in the development of autism" (Tr. 950), yet her testimony provided no explanation as to *how* that variant made W.R. more susceptible to harm from the aluminum adjuvants in his vaccinations (Tr. 949-51). In a similar fashion, Dr. Mikovits provided no cogent explanation as to *how* W.R.'s "CCL2" variant made him more susceptible to harm from the aluminum in his vaccinations, limiting her testimony to merely opining that that variant was another *risk factor* that could cause W.R.'s alleged "immune deficiency" (Tr. 951) and "brain inflammation" (Tr. 952). Overall, Dr. Mikovits simply provided a cursory opinion that W.R.'s "CCL2" and "MTHFR" variants were "risk factors" (Tr. 952) that played a role in W.R.'s injuries, without a cogent explanation or elaboration as to *how* those variants caused W.R. to be more susceptible to harm from his vaccinations (Tr. 952-59).

In contrast, Dr. Shaw pointed only to *one* of W.R.'s variants -- his "CCL2" variant -- opining that that variant "probably" rendered W.R. more susceptible to the harmful effects of aluminum. (Tr. 101.) However, his subsequent testimony regarding the *type* of injuries that the "CCL2" gene variant could cause provided only vague speculation concerning one specific neurological disorder called "macrophagic myofasciitis"-- a neurological disorder that the Petitioners have *not* alleged that W.R. suffers from. (Tr. 101-03.)

On the other hand, Dr. Ratajczak pointed only to W.R.'s "MTHFR" gene variant, opining that that variant, when "paired with environmental factors" could have made W.R. "more susceptible" to developing autism. (Ex. 216, p. 1, emphasis added.) Her ensuing explanation as to *how* W.R.'s "MTHFR" gene variant could have brought about W.R.'s autism, however, was very unclear, and seemed to suggest that that variant "affected the development of [W.R.'s] immune system" (*id.*), which, due to "environmental factors," such as the aluminum contained in vaccines, somehow led to W.R.'s autism (*id.*, p. 2). Similar to Dr. Ratajczak, Dr. Seneff also pointed exclusively to W.R.'s C677T "MTHFR" gene variant (Ex. 88, p. 2), portraying that variant as causing an impairment in W.R.'s "ability to detoxify aluminum" (*id.*), which, according to Dr. Seneff, allowed for aluminum "to infiltrate the brain and damage neurons" (*id.*).

Moreover, Dr. Deth provided very vague testimony on the issue of how W.R.'s genetic variants allegedly made him more susceptible to harm from his vaccinations. In this regard, Dr. Deth simply resorted to making references to the fact that W.R. "carries genetic risk factors," and opined that those risk factors somehow placed W.R. at an "increased risk for impaired methylation," which, in combination with W.R.'s vaccinations, caused W.R.'s "impaired development." (Tr. 361.)

Irrespective of the disjointed theories of the Petitioners' experts discussed above, however, I found Dr. Wiznitzer's overall rebuttal of those experts on this issue to be *far more* persuasive. I begin by noting that, although Dr. Wiznitzer mainly offered a rebuttal to Dr. Megson's opinion on this issue -- that is, he strongly refuted Dr. Megson's opinion that either the "CCL2" or the "MTHFR" gene variants caused W.R. to be more susceptible to harm from the aluminum contained in his vaccinations -- his *overall testimony* regarding those two variants within W.R. was effective in rebutting *all* of the Petitioners' experts' disjointed theories on this point. In this regard, I find Dr. Wiznitzer's testimony concerning W.R.'s gene variants to be far more logical and convincing than that of the Petitioners' experts.

First, Dr. Wiznitzer addressed the "MTHFR" gene variant, opining that that variant was "present in a significant percentage of the population." (Tr. 827.) In terms of the functional differences of the "MTHFR" gene variant in a population, as compared to those who have the normal gene, Dr. Wiznitzer opined that that variant does not have a "major impact" in people carrying that variant, even to the extent that the "mainstream medical community" does not recommend that people carrying that variant take supplements to rectify any potential harms from that variant. (Tr. 828.) In this regard, Dr. Wiznitzer explained that *if*, as theorized by Dr. Megson, the "MTHFR" gene variant affected "folic acid" and "folic acid replacement" functionality in people carrying that variant, then he would "expect to see differences" in laboratory testing markers for "methionine" and "homocysteine." (*Id.*) In contrast, however, he pointed out that W.R. "had totally normal values when those things were tested in the lab." (*Id.*) In other words, Dr. Wiznitzer pointed out that W.R.'s medical records flatly rejected Dr. Megson's theory that the "MTHFR" variant induced any negative effects in W.R.'s case specifically.

Second, Dr. Wiznitzer addressed the "CCL2" gene variant, refuting Petitioners' expert's disjointed theories that that variant somehow led to a "greater risk for aluminum transport or aluminum going to the brain." (Tr. 828.) In this regard, he pointed to an item of *Petitioners' own*

medical literature submitted in this case -- Ex. 128 (Khan *et. al.*)[65] -- to refute the opinions of Petitioners' experts concerning that variant. (Tr. 828-29.) Dr. Wiznitzer opined that, upon his review of the supplementary appendix referenced in the Khan article (*see* Ex. 128, p. 16), he found that the data set used in that study showed *no statistical differences* between the groups of patients who had the "CCL2" gene variant and the control group who did not have that variant. (Tr. 828-30.) Thus, upon his close review of the appendix clarifying the data set that Ex. 128 was based upon, Dr. Wiznitzer emphatically stated that the "CCL2" gene variant "means nothing" (Tr. 830), further classifying that variant simply as "a gene variant that we find in the general population" (Tr. 831).

In summary, Dr. Wiznitzer opined that "neither the MTHFR gene variant or the CCL2 gene variant mean anything in a functional manner" (Tr. 832), and that Dr. Megson's opinion to the contrary -- that is, an opinion stating that those two variants caused W.R. to be more susceptible to harm by the aluminum in his vaccinations -- had "no scientific support" (*id.*). In this regard, I find Dr. Wiznitzer's testimony, concerning those two variants, to be *far more* persuasive than Dr. Megson's presentation, along with Drs. Shaw, Mikovits, Deth, Ratajczak, and Seneff's presentations concerning this point. I find that the Petitioners' experts wholly *failed* to establish this part of their theory in this case.

XIII

PETITIONERS' EXPERTS' TESTIMONY CONCERNING POSSIBLE "MITOCHONDRIAL DYSFUNCTION" DID NOT SUPPORT PETITIONERS' OVERALL CAUSATION CLAIM

Most cells in the human body contain "mitochondria," which supply energy to the cell.[66] Several of Petitioners' experts in this case -- including, Drs. Megson, Mikovits, Deth, Goh, and Seneff -- indicated at different times that W.R. has a "mitochondrial dysfunction," or a "mitochondrial impairment," which purportedly made W.R. more susceptible to injury by vaccination. (*E.g.*, Ex. 104, p. 3; Tr. 28, 43, 194-95; Ex. 88, p. 3, Ex. 242, p. 22; Ex. 150, p. 1.)

However, after studying the entire record of this case, I conclude that Petitioners and their experts have *failed* to show that it is "more probable than not" that W.R. has "mitochondrial dysfunction," or any disorder which impairs the proper functioning of his mitochondria, for the reasons stated below.

I first note that the Petitioners' experts were themselves inconsistent regarding the *exact evidence* upon which they relied to support their diagnostic opinions that W.R. allegedly suffered from "mitochondrial dysfunction," or "mitochondrial impairment." For example, Drs. Megson, Mikovits, and Seneff mainly pointed to W.R.'s *laboratory findings*, as apparent support for their opinions that W.R. has mitochondrial dysfunction. In this regard, Dr. Megson pointed to W.R.'s

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[65] The transcript of this case misspells the lead author of Ex. 128 as "Kahn." (Tr. 828.) However, the correct spelling of the lead author of Ex. 128 is "Khan." (Ex. 128.)

[66] DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (32nd ed. 2012), p. 1169.

"high lactate and pyruvate" markers -- classifying those markers as being "markers for mitochondrial dysfunction." (Tr. 28; *see also* Ex. 104, p. 8.) Similarly, Drs. Mikovits and Seneff also pointed to W.R.'s elevated marker for "lactate" as support for their diagnosis of mitochondrial dysfunction (Tr. 195; Ex. 88, p. 3), with Dr. Mikovits even testifying at the evidentiary hearing that "the lactate primarily is the one that we measure" in making an assessment of whether an individual has mitochondrial dysfunction (Tr. 195).

On the other hand, Dr. Goh pointed to W.R.'s laboratory testing results *and* to his *clinical features* to provide support for her mitochondrial assessment in this case. In this regard, although Dr. Goh pointed to the same "elevated blood lactate level" laboratory findings as the Petitioners' experts mentioned above (Ex. 150, p. 2), she also made vague references to the "[m]any clinical features" of W.R. that purportedly pointed to W.R. having "mitochondrial impairment" that was subsequently "exacerbated by vaccination" (*id.*, p. 1). In this regard, Dr. Goh relied upon *statements made by Mrs. Rogero* alleging that, after W.R.'s DTaP vaccination at 19-months of age, he "was only making guttural sounds," "stopped babbling with inflection," "no longer made any attempt to say words," and that he "stopped waving and pointing." (*Id.*, p. 2.) However, Dr. Goh *wholly failed* to provide citations to W.R.'s *contemporaneous medical records* to support her statement that "[m]any clinical features" pointed to W.R. allegedly having "mitochondrial impairment," or a "disturbance of mitochondrial function."

Moreover, irrespective of the inconsistencies of the Petitioners' expert opinions concerning the exact evidence that pointed to W.R. having an alleged "mitochondrial dysfunction" or "mitochondrial impairment" discussed above, however, I found Dr. Cohen's overall rebuttal of those experts on this issue to be *far more persuasive.*

I begin by noting that Dr. Cohen is far better qualified than Drs. Megson, Goh, Seneff, Deth, and Mikovits to opine concerning *mitochondrial diseases*, since Dr. Cohen is a *medical doctor* who has devoted much of his career to *specializing* in mitochondrial diseases. Dr. Cohen has extensive experience treating patients with mitochondrial diseases, most notably concentrating in his practice at The Cleveland Clinic for more than 21 years upon treating patients with mitochondrial diseases. (Ex. E, p. 1.) In his current role as the Director of the Neurodevelopmental Science Center of Akron Children's Hospital, the overwhelming majority of his clinical practice -- "approximately 90%" -- is comprised of patients suffering from various mitochondrial diseases. (*Id.*, p. 2.) Moreover, Dr. Cohen has been elected by his peers to serve in various leadership roles in societies devoted to the areas of mitochondrial medicine and child neurology, including serving as the President of The Mitochondrial Medicine Society (*id.*, p. 2), and directing and co-directing "ten international symposiums on mitochondrial medicine, sponsored by The United Mitochondrial Disease Foundation (UMDF)" (*id.*). Dr. Cohen has extensively engaged in research and published in the field of mitochondrial disease spanning "over 90 peer-reviewed publications" and "dozens of book chapters" (*id.*, p. 3), and has been invited to present "over 580" lectures in that specialty (*id.*).

Overall, Dr. Cohen opined persuasively that, based on his evaluation of W.R.'s contemporaneous medical records, W.R. "does not have a mitochondrial illness or disease." (Ex. E, p. 8.) Moreover, Dr. Cohen stated in his expert report that, based upon his review of W.R.'s contemporaneous medical records, the "sequence of events" in W.R. is "very consistent with what is seen in many cases of childhood autism," further stating that "there is nothing about

these events that would hint at an acute or chronic neurodegenerative process or a mitochondrial illness." (*Id.*, p. 9.)

Furthermore, Dr. Cohen effectively refuted Petitioners' experts' reliance on W.R.'s elevated lactate levels in certain of his laboratory tests. In this regard, Dr. Cohen pointed out that "[l]actic acid elevation without other features is *never* diagnostic of mitochondrial dysfunction." (Ex. E, p. 9, emphasis added.) He acknowledged that W.R. had "two mild elevations of blood lactic acid (and pyruvic acid)" (*id.*, p. 10), and that generally, the "blood lactate" test "can be a marker of mitochondrial dysfunction" (*id.*). However, he put those results in their proper context by explaining that it was "accepted by the medical community that [the blood lactate test] is known to give false-positive results, especially in children." (*Id.*) Thus, he explained, in pediatric populations, an "amino acid test," among other tests, is generally ordered *in conjunction with* the blood lactate test to properly assess the existence of a mitochondrial problem in pediatric patients. (*Id.*) Moreover, he pointed out that *several other* amino acid markers would be elevated in typical patients with mitochondrial problems, stating that those "blood amino acids were not suggestive of any mitochondrial dysfunction or oxidative stress" in W.R.'s case. (*Id.*, p. 11.)

Additionally, Dr. Cohen pointed out an important fact from W.R.'s contemporaneous medical records -- that "[a]dditional biochemical and/or specific mitochondrial testing was *not* performed" by any of W.R.'s treating physicians. (Ex. E, p. 11, emphasis added.) He particularly emphasized that such additional testing was not conducted by two specific doctors that treated W.R. -- Drs. Summar and Gropman -- doctors who, according to Dr. Cohen, are "two of the most senior members of the metabolic and mitochondrial academic community." (*Id.*) In this regard, he opined that such testing was presumably not conducted by Drs. Summar and Gropman because they "did not feel this was necessary based on the child's medical presentation" (*id.*). This critical point by Dr. Cohen was left *unrefuted* by any of Petitioners' experts who subsequently testified at the evidentiary hearing.

Additionally, Dr. Cohen thoroughly explained the diagnostic steps necessary in "[e]stablishing a mitochondrial diagnosis" (Ex. E, p. 9), and thereafter meticulously outlined how W.R. did not fit the criteria for having a mitochondrial illness (*id.*, pp. 9-11). In summary, Dr. Cohen stated that W.R. "does not have a mitochondrial illness, nor ongoing mitochondrial dysfunction" (*id.*, p. 11), and that his "presentation is most consistent with the presentations of children with autism" (*id.*).

As such, the record of this case indicates that the Petitioners' experts opining that W.R. has either a "mitochondrial dysfunction," or "mitochondrial impairment," or that he suffers from a "disturbance of mitochondrial function," are quite wrong in this part of their opinions, and I find Dr. Cohen's opinion on this issue to be very persuasive.

XIV

DR. CIVITELLO'S LETTER DOES NOT CHANGE MY CONCLUSION

As previously noted, Petitioners filed an opinion letter of Dr. Lucy Civitello, who was W.R.'s treating neurologist for an unclear period of time, starting in 2010. (*See* Ex. 102, p. 1; *see also* Ex. 9, p. 154.) Dr. Civitello did not supply an affidavit, or testify at the evidentiary hearing. Instead, in a letter addressed "To Whom It May Concern" dated September 23, 2013, Dr. Civitello stated the following about W.R.'s developmental trajectory: [AND 5 YEARS OF RECORDS]

> There were no difficulties at birth and he was noted to have developmental delays later on in life. He has also had loss of abilities over time, particularly verbal abilities. These regressions have typically occurred following vaccination.

(Ex. 102, p. 1.) That letter also opined as follows:

> In summary, [W.R.] has a diagnosis of a **chronic encephalopathy manifested by speech disorder, oral motor dyspraxia, hypotonia, and motor delays**. The etiology is not known at this time, although we have ruled out multiple medical conditions as noted above;

(Ex. 102, p. 1.) Therefore, Dr. Civitello's letter *seems* to suggest that W.R.'s neurodevelopmental disabilities occurred later in life and that he had regressions after each set of vaccinations in the early years of life. [HER MEDICAL RECORD STATES ONLY MAY 2010 DTAP REGRESSION] Dr. Civitello's *curriculum vitae* was not submitted in this case; however, from the medical records submitted within the case, I gather that she is a pediatric neurologist, holds a position at Children's National Hospital in the Washington, D.C. area, and has treated W.R. (*E.g.*, Ex. 6, pp. 22-24; Ex. 9, pp. 3-5, 7-9; Ex. 43, 60-62; Ex. 45, pp. 14-16.) Accordingly, I have given her letter careful consideration. However, in my final analysis, I find that Dr. Civitello's letter offers no substantial support to Petitioners' causation claim, and is strongly outweighed by the rest of the evidence in the record concerning the diagnosis and causation issue, particularly the testimony of Dr. Wiznitzer. [DR. WIZNITZER FILED REGRESSION IN REPORT FROM MEDICAL RECORDS AND OPINED OF HIS MOTOR ISSUES ARE ENCEPHALOAPTHY AND HIS AUTISM WAS "LATER"] [DR.CIVETELLOS 5 YEARS OF MEDICAL RECORDS ARE ABSENT THIS DECSION] Most importantly, I note that not only did Dr. Civitello not submit an affidavit or testify, but she also did not set forth in her written letter any detailed *explanation* concerning *why* she wrote that W.R. suffered regressions after each set of his administered vaccinations. In this regard, her statement does not even mention at exactly what time W.R. allegedly started experiencing neurodevelopmental disabilities, nor does it mention *which* vaccinations preceded W.R.'s alleged regressions, and in what time period after his vaccination those alleged regressions occurred. Since Dr. Civitello did not start treating W.R. until 2010, clearly she did not have personal knowledge of the alleged "regressions." Most likely, her statement that regressions occurred after vaccinations was merely a notation of what *W.R.'s parents* told her.
[SEE CAPIZZANO, A SPECIAL MASTER ERRS WHEN NOT USING TREATING MD RECORDS] Further, Dr. Civitello's letter absolutely does not indicate in any way that *she believed* that any of W.R's conditions were *related to vaccinations*. To the contrary, she stated in the letter

that his conditions are of "unknown etiology," and repeated that their "etiology is not known." (Ex. 102, p.1.) IT STATES MEDICAL ETIOLOGY BECAUSE SHE RULED OUT OTHER CAUSES IN CONTEXT. HE RECORD DOCUMENTS REGRESSION AFTER MAY DTAp LISTING THE SKILLS]]

Finally, even if Dr. Civitello's letter offered any support to Petitioners' causation theories, I would necessarily need to give Dr. Civitello's opinion regarding W.R.'s apparent

diagnoses and regressions far less weight than the opinion of *Dr. Wiznitzer*, who not only wrote a detailed report refuting Petitioners' assertions regarding W.R.'s apparent regressions, but testified in order to *explain* his views at length, and was able to do so in a highly persuasive manner. In this regard, I put more weight on the testimony of Dr. Wiznitzer, who stated that Dr. Civitello's letter cannot be taken in isolation, and pointed out several flaws with that letter. (Tr. 813-14.) Most importantly, Dr. Wiznitzer pointed out that Ex. 102 did not cite to *contemporaneous medical records* supporting the notion that W.R. suffered "regressions" soon after vaccinations. (*Id.*)

In short, while I have not ignored Dr. Civitello's opinion letter, I found that it was strongly outweighed by all of the contrary evidence in this case. [USING THE CONTEMPORANEOUS ONSET OF ENCEPHALAOPTHY MEDICAL RECORDS WOULD FOLLOW THE RULES OF THE VACCINE COURT OF MASTER TO USE THE RELEVANT EVEIDENCE IN FAIRNESS TO BOTH PARTIES]

XV

PETITIONERS' EXPERTS' ADMISSIONS AS TO THE TENTATIVE AND SPECULATIVE NATURE OF THEIR OWN THEORIES

I also note that many of Petitioners' experts' own statements acknowledged the *tentative* and *speculative* nature of various aspects of their causation theories. Actually, some of the Petitioners' experts in this case -- Drs. Shaw (Ex. 86, p. 1; Tr. 96); Palevsky (Tr. 447); Exley (Ex. 99, p. 3; Tr. 703-04); and Goh (Ex. 150, p. 1) -- seemed merely to be *throwing out possibilities* as to the cause of W.R.'s conditions, yet failing to explain any of these opinions persuasively.

[ALTHEN COURT STATES REQUIRING PROOF OF A MECHANISM IS INCONSISTENT WITH THE PROGRAM]

For example, I note that Dr. Exley admitted that he did not know the *mechanism*[67] of how aluminum adjuvants contained in vaccines could have worked to cause W.R.'s neurodevelopmental disabilities (Tr. 655), and was able only to provide vague discussions of several *possible* mechanisms that could be applicable in this case (Tr. 676). Similarly, at several instances during his evidentiary hearing testimony, Dr. Exley seemed to merely *postulate potential* ways that aluminum contained in vaccinations *might* infiltrate the human body and reach the brain (Tr. 656, 668-75). Moreover, Dr. Exley admitted that several critical components of his expert opinion in this case were still at an experimental level (Tr. 704), or were *merely assumptions* that needed to be tested in the future (Tr. 711).

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67 To be sure, a petitioner need *not* necessarily show the *mechanism* of injury. If a petitioner can show, based upon the overall record, that an injury was "more likely than not" caused by a vaccination, then that petitioner becomes entitled to a Program award whether or not the *mechanism* of injury is demonstrated. However, an expert's failure to point to a *mechanism* of injury can be *one factor* to consider in determining whether that expert's causation theory was persuasive. In this case, I found Dr. Exley's *overall presentation* to be speculative and less persuasive than the presentation of Respondent's expert, Dr. Cetaruk, who rebutted his testimony. Based on the entire record, I do not find it to be "more probable than not" that any of W.R.'s vaccines containing aluminum adjuvants caused, or aggravated, any of W.R.'s conditions, by *any* mechanism.

Similarly, while Dr. Ratajczak opined in her expert report and testimony that Mrs. Rogero's flu vaccination of November 26, 2008, *could* have also harmed W.R., opining that he was likely to have been exposed to the mercury contained in that flu vaccination via breast-feeding (Tr. 631-34; Ex. 216, p. 3), she acknowledged in her expert report that her theory, regarding the harmful effects of Mrs. Rogero's mercury-containing flu vaccination, was only something that *theoretically could be possible* (Ex. 216, p. 3).

Thus, as these examples illustrate, I note that five of the Petitioners' experts in this case – Drs. Shaw, Palevsky, Exley, Goh and Ratajczak -- in essence acknowledged the sheer speculativeness of their theories on both the general and specific causation issues in this case. Thus, at base, the expert opinions of those experts were essentially exercises in merely suggesting *potential* theories, without any persuasive evidence for them.

XVI

THE MEDICAL LITERATURE SUBMITTED BY PETITIONERS DID NOT ADD MUCH SUPPORT TO ADVANCE THEIR CLAIM

[DTAP PRESCRIBING INFORMATION WAS FILED IN 2013 AND NOT REQUIRED BY THE ACT]

I additionally note that, throughout this litigation, Petitioners have submitted numerous articles, in most cases without proper explanation or analysis as to the particular relevancy of those articles as to the general and specific causation issues in this case. Moreover, upon my examination of the articles submitted as "medical literature" by the Petitioners in this case, I note that many of those articles either: (1) *contradict* certain positions of the Petitioners' experts and their counsel; (2) are irrelevant to the issues in this case; (3) are *not* supportive of the proposition that the experts cite those articles for; (4) are merely abstracts of full-length articles, thus making it difficult to discern the context of those articles; or (5) are simply *opinions* of some of the *very experts* testifying in this case.

Thus, although I have closely reviewed all of the submissions labeled as "medical literature" in this case, I find that, as a whole, those submissions were of little value in supporting the overall general and specific causation issues advanced by the Petitioners in this case.

XVII

TESTIMONY AND FILINGS OF MRS. ROGERO

In my review of Mrs. Rogero's affidavits, her testimony at the evidentiary hearing, and the various documents prepared by Mrs. Rogero that have been filed in this case, I find that they conflate her role as a Petitioner in this case with the role performed by Petitioners' experts. That is, Mrs. Rogero's statements throughout this litigation sometimes veered into medical opinion testimony, offering her own opinions regarding medical and scientific issues that are central to this case. To be sure, I have great sympathy for Mrs. Rogero, as well as her husband, and their

tragically disabled child. But, I note, of course, that Mrs. Rogero is not a medical doctor, and has no credentials to opine on the vaccine-causation issues in this case. Thus, while I have closely

examined Mrs. Rogero's written and oral testimony opining on the diagnostic and causation issues in this case -- including, among other things, carefully reviewing the document labeled "Appendix A" submitted by Petitioners on March 6, 2017 -- I find those statements to be thoroughly unpersuasive, and deem them to be far outweighed by the opinions of the Respondent's experts.

In addition, I note that Mrs. Rogero made numerous statements, in her oral testimony and her filings in this case, alleging improper actions by Respondent's attorneys and experts. But I have carefully reviewed the record and find no evidence of any improper conduct by Respondent's attorneys or experts.

XVIII

PETITIONERS' ARGUMENT THAT THIS IS "NOT AN AUTISM CASE"

As previously explained, W.R.'s medical records show that he has been definitively diagnosed with an autism spectrum disorder (ASD). AND AN ENCEPHALOPATHY, AND THE GOVERNEMENT OPINED HIS AUTISM WAS SUBSEQUENT TO AND LATER THAN HIS ENCEPHLOPATHY Further, this case arises in the context of a situation in which thousands of Vaccine Act petitions have alleged that a child's *ASD* was vaccine-caused. (See Section II above.) THISIS NOT THIS CASE – SEE AFFIDAVIT AND NO FINDING OF A CLAIM OF AUTISM, THE DECSION FINDS IT IS SEQUELAE OF ENCEPHALAOPTHY, LEGALLY MEANING CAUSED BY ENCEPHALAOPTHY And my discussion above (Section II) demonstrates that prior Vaccine Act petitions have been *uniformly unsuccessful* in attempting to demonstrate that any child's ASD, or that child's "autistic-like symptoms," have been vaccine-caused. FOCUSING ON HIS SUBSEQUENT AUTISM IS DISCRIMINATORY WITH A VACCINE-RELATED ENCEPHLOPATHY AS THE CLAIM

In this context, Petitioner's counsel has, at several points in this case, insisted that "this case is not about autism. *** [T]his case is about encephalopathy that was caused by the vaccinations *** [in which] the sequelae [of the encephalopathy] may include autism or autistic- like symptoms." (*E.g.*, Pet. Post-Hearing Brief, filed 8-19-16, pp. 1-2.) **[1003.(d0(3)]**

This sort of argument, of course, is not a new one. THIS WAS NOT OUR ARGUMENT, AND NOT OUR CASE In many of the cases involving children with ASDs decided since 2010 (see Section II above), petitioners have tried to avoid the conclusions of the autism "test cases" by alleging that a child suffered a vaccine-caused "encephalopathy" that resulted in "autistic-like features," THAT IS A HOLDING OF CHIEF SPECIAL MASTERS AND CASE LAW, AS DEFINED BY SEQUELAE IN THE ACT or that a child had an underlying "mitochondrial disorder" HAS A DIAGNOSIS OF DYSFUNCTION or "genetic variants" that somehow made the child more vulnerable to injuries by vaccines, or that an "autoimmune" process was involved. But all such cases, *in essence*, have amounted to attempts to prove that vaccines can cause or aggravate *symptoms of ASDs*. And, all such theories have been *rejected*. THER IS NO CLAIM OF AGGRAVATING, CAUSING OR OTHERWISE ASD, A BEHAVIORAL DIAGNOSES

In this case, like so many of the cases listed in Section II above, Petitioners' argument in this regard is unavailing. While I have set forth Section II above to show the *context* in which this case was filed and litigated, I have evaluated the *specific arguments* advanced by Petitioners' experts *in this case*. I have considered whether Petitioners have shown that W.R. suffered an "encephalopathy" caused by his vaccinations, but find that Petitioners have *completely failed* to make such a showing. They have failed to show that the aluminum in vaccines harmed W.R. in any way. They have failed to show that W.R's genetic variants made him susceptible to brain injury by vaccinations. They have failed to show that he had either an immune disorder or a mitochondrial disorder that made him susceptible to injury by vaccinations.

In short, the outcome of this case would be no different if W.R. had never been diagnosed with an ASD.[68]
[BECAUSE THE CLAIM NEVER HAD DUE PROCESS AND AUTISM WAS NOT A CLAIM]

[68] In this regard, however, it is also worth noting that, Petitioners' expert, Dr. Megson stated during her hearing testimony her belief that W.R.'s primary ~~neurodevelopmental disorder~~ should *not* be considered as being an autism spectrum disorder (Tr. 35-37), but, rather, as an "encephalopathy" (Tr. 37). However, based upon the record of this case, I conclude that Dr. Megson is simply wrong on this point. [ERRONEOUSLY CONTRADICTS THE TRANSCRIPT HERE, AND THE SPECIAL MASTER IS NOT TO DIAGNOSE VACCINE-RELATED INJURIES, PRECEDENT KNUDSEN]

First, as explained above in Section VIII(A)(1)(A), Dr. Wiznitzer is far better qualified than Dr. Megson to opine concerning the topic of autism. And Dr. Wiznitzer testified persuasively that, based on his evaluation of W.R.'s medical records, W.R. "clearly has an autism spectrum disorder." (Tr. 814.) Dr. Wiznitzer defined an "autism spectrum disorder" as a "neurobiological disorder that affects socialization and social communication" (Tr. 815), and opined that W.R. fits within this "core criteria" (Tr. 816), as W.R. does not (1) use language in any meaningful way and (2) does not interact, or show an interest in his peers (Tr. 816-17).

Moreover, Dr. Wiznitzer explained that W.R.'s medical records reflect that W.R. showed several classic behaviors commonly exhibited in the autism population that he treats, including (1) being "more interested in the object than the person" with whom he is interacting (Tr. 817); (2) liking to "play with toys that have cause/effect mechanism" (*id.*); and (3) the lack of response when people are calling his name (Tr. 818.) **[DR. WIZBITER OPINED OF HIS ENCEPHALOAPTHY AND THAT HIS AUTISM WAS LATER AND FOCUSED ON POST DTAP RECORDS, SEE REBUTTAL]]**

Furthermore, Dr. Wiznitzer defined "encephalopathy" [CONTRARY TO THE VACCINE ACT AND SUPREME COURT LAW] as when "the brain isn't working right," and explained that in "autism the brain isn't working right." (Tr. 819.) Thus, he opined that W.R. "has an encephalopathy *because* he has an autism spectrum disorder" (Tr. 819, emphasis added), and that W.R.'s clinical presentation was typical for patients with an ASD (Tr. 820-21). (Of course, Dr. Wiznitzer stressed that W.R.'s "encephalopathy" -- *i.e.*, his ASD -- was clearly *not* caused by any vaccinations.) In this regard, he explained that certain of W.R.'s symptoms that Dr. Megson asserted distinguished his case from being within the autism spectrum -- such as W.R.'s oral motor dyspraxia and other similar "praxis" problems -- were, in fact, problems that were "very common in the ASD population." (Tr. 821.).

Further, Dr. Wiznitzer, pointed out several instances in W.R.'s medical records where his own *treating physicians* identified W.R. as having an autism spectrum disorder, including his geneticist, Dr. Gropman, and his neurologist, Dr. Civitello. (Tr. 818-19.) *See also* W.R.'s records -- W.R. said to have "autism" by Dr. Stevens (Ex. 5, p. 3); "autism" diagnosed by Dr. Panitz (Ex. 6, p. 5); "autistic disorder" diagnosed by Dr. Legarda (Ex. 28, p. 14). [YES THEY DOCUMENTED HE HAS BOTH DIAGNOSES]

In short, the record of this case indicates that Dr. Megson is *quite wrong* in this part of her opinion, while I find Dr. Wiznitzer's opinion on this issue to be very persuasive. Contrary to the opinion of Dr. Megson, W.R. clearly does suffer, tragically, from an autism spectrum disorder.

XIX

NOTE CONCERNING PETITIONERS' MANY ALLEGATIONS AND THEORIES

I note that at various places in the record of this case, Petitioners' counsel, Petitioners' experts, or Mrs. Rogero herself have alleged that W.R.'s vaccinations caused *a number of different injuries to W.R.*, and also alleged a number of *alternative theories* as to how such alleged injuries occurred. But I conclude, after studying the entire record of this case, that Petitioners have failed to show that it is "more probable than not" that *any* vaccination or vaccinations injured W.R. in *any* way. [RECHALLENGE EVIDENCE IS PROOF OF PRONG TWO – THE MEDICAL THEORY IS THE 4th DTAP IN THE RECHALLENGE CAUSING THE VACCINE-RELATED ENCEPHALOAPTHY]

Of course, most of the presentations of Petitioners' experts were devoted to the *aluminum adjuvant* in the vaccines that W.R. received in his early months of life, alleging that such aluminum caused W.R. to suffer an "encephalopathy" (brain injury) that resulted in the symptoms that caused him to be diagnosed with an Autism Spectrum Disorder (ASD). But on the basis of the entire record, I find that Petitioners have *failed* to demonstrate that the aluminum in vaccines *can* contribute to the causation of *ASDs*, or any types of "encephalopathy" or brain disorder, [69] or that W.R.'s aluminum-containing vaccines *did* initially cause or aggravate *W.R.'s own* "ASD," by means of causing an encephalopathy in W.R.

Petitioners have failed to demonstrate many sub-parts of their causation theory, such as the allegations that W.R.'s genetic variants made him more susceptible to injury by aluminum or other parts of vaccinations, or that he has a defective immune system, or that he has a mitochondrial disorder. I also conclude that Petitioners have failed to show that any of his vaccinations caused any *immunological* or *other* injuries to W.R.

XX

PETITIONERS HAVE FAILED THE *ALTHEN* TEST

[THE SPECIAL MASTER NEVER APPLIED ALTHEN TO THE CLAIM HE FOUND IN ADJUDICATIVE FINDINGS – DTAP CAUSAL TO ENCEPAHLAOTPHY]

As noted above, in its ruling in *Althen*, the U.S. Court of Appeals for the Federal Circuit discussed the "causation-in-fact" issue in Vaccine Act cases. The court stated as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

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[69] See also *Olson v. HHS,* No. 13-439V, 2017 WL 3624085 (Fed. Cl. Spec. Mstr. July 14, 2017), in which Special Master Corcoran rejected a claim that the aluminum adjuvant in a vaccination harmed the vaccinee.

Althen, 418 F.3d 1274, 1278 (Fed. Cir. 2005)(citations omitted). In the pages above, of course, I have already set forth in detail my analysis in rejecting Petitioners' "causation-in-fact" theory in this case. In this part of my Decision, then, I will briefly explain how that analysis fits *specifically* within the three parts of the *Althen* test, enumerated in the first sentence of the *Althen* excerpt set forth above. The short answer is that I find that Petitioners' theory in this case clearly does not satisfy *any part of* the *Althen* test.

A. Relationship between Althen Prongs 1 and 2

One interpretive issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that the petitioners must provide "(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." Initially, it is not absolutely clear how the two prongs differ from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between "the vaccination" and "the injury." However, a number of Program opinions have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions issued prior to *Althen* involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the *particular* vaccination received by the specific vaccine *did* cause the vaccinee's *own* injury. *See, e.g., Kuperus v. HHS*, No. 01-60V, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, No. 96-518V, 2002 WL 31441212, at *18 n. 42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the "can cause" requirement, and Prong 2 of *Althen* is the "did cause" requirement. *See, e.g., Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, No. 02-738V, 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, No. 06-120V, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30, 2008). And, most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the "can it?/did it?" test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. *Pafford v. HHS*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the type of vaccination in question can cause the type of condition in question; and under Prong 2 of *Althen* that petitioner must then demonstrate that the particular vaccination did cause the particular condition of the vaccinee in question.

Moreover, there can be no doubt whatsoever that the *Althen* test ultimately requires that, as an overall matter, a petitioner must demonstrate that it is "more probable than not" that the particular vaccine was a substantial contributing factor in causing the particular injury in question. That is clear from the statute itself, which states that the elements of a petitioner's case must be established by a "preponderance of the evidence." § 300aa-13(a)(1)(A). And, whatever is the precise meaning of Prongs 1 and 2 of *Althen,* in this case the overall evidence falls far short of demonstrating that it is "more probable than not" that any of the vaccines that W.R. received contributed to the causation of any of W.R.'s tragic neurodevelopmental conditions, or any of his alleged autoimmune illnesses.

B. Petitioners have failed to establish Prong 1 of Althen in this case.

As explained above, under Prong 1 of *Althen* a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause the *type* of condition in question. The chief allegation of the Petitioners in this case is that the cumulative set of vaccines administered to W.R. in his early months of life contributed to the **causation of W.R.'s tragic developmental disorder**, in the context of his various genetic variants, and/or his alleged underlying defects in mitochondrial or immunological function. Petitioners allege in particular that the *aluminum adjuvants* contained in those vaccinations [MECHANISM] were the chief source of this alleged vaccine-caused injury. However, as discussed in Sections VIII, IX, X, and XV above, Petitioners have *not come close* to demonstrating that the aluminum adjuvants in vaccines *can cause* neurological injury, even in the context of either a genetic variant or an underlying mitochondrial or immunological dysfunction, or that aluminum adjuvants *can cause* various autoimmune illnesses. As explained, the Petitioners' expert reports and expert testimony simply contained no significant scientific evidence establishing that the aluminum-adjuvant-containing vaccines *can cause* the types of neurological or the alleged autoimmune injuries that W.R. suffers from, under *any* circumstances. Thus, Petitioners' claim clearly fails under Prong 1 of *Althen*. **[DOJ for HHS filed the overall theory is DTaP causal to Encephalopathy by Dr. Megson's opine quoting the medical records.]**

C. Petitioners have failed to establish Prong 2 of Althen in this case.

Under Prong 2, the Petitioners need to show that it is "more probable than not" that W.R.'s vaccinations containing aluminum adjuvants *did* contribute to the causation of one or more of *W.R.'s own* neurologic or autoimmune conditions. But this they have failed to do, for all of the reasons detailed above. Having failed to demonstrate Prong 1, Petitioners logically cannot have shown Prong 2, for the same reasons. Further, as demonstrated in Section VII of this Decision, their claim must fail Prong 2 because Petitioners' expert relied upon *incorrect factual assumptions* about W.R.'s medical history. In addition, as explained above, the Petitioners also failed to demonstrate that W.R. even has mitochondrial dysfunction or an autoimmune illness -- important factual predicates for their causation opinion. (*See* Section XI and XIII.) And my discussions in Sections XIV, XVII, XVIII, and XIX also demonstrate Petitioners' error as to Prong 2. Thus, Petitioners have failed to establish Prong 2 of *Althen* in this case.

D. Petitioners have failed to establish Prong 3 of Althen in this case.

Since I have explained why Petitioners have failed to satisfy the first and second prongs of *Althen*, I need not discuss why Petitioners' case also fails to satisfy the *third* prong. However, I note that as to Prong 3, under which Petitioners need to establish a proximate *temporal relationship* between the vaccination and the injury, I have demonstrated in Section VII above that Petitioners' experts made *incorrect* factual assumptions as to the alleged temporal relationships between W.R.'s vaccinations and his alleged "regressions." Thus, Petitioners have clearly failed to establish Prong 3 as well.

E. This is not a close case.

As noted above, in *Althen* the Federal Circuit indicated that the Vaccine Act involves a "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." 418 F.3d at 1280. Accordingly, I note here that this case ultimately is *not* a close case. For all the reasons set forth above, I found that the litany of theories presented by Petitioners in this case were *not at all* persuasive, while Respondent's experts were *far* more persuasive.

XXI

CONCLUSION

The record of this case demonstrates plainly that W.R. and his family have been through a tragic ordeal, and I have great sympathy for the family. However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of those individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or by a preponderance of "causation-in-fact" evidence, to a listed vaccine. In this case, the evidence advanced by the Petitioners has fallen far short of demonstrating such a link. Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award on W.R.'s behalf.[70]

[SEE DR MEGSON, PALEVSKY, GOH, SENEFF... – DTAP CAUSAL TO ENCEPHALOAPTHY IN THIS DECISION, NEVER HAD DUE PROCESS]

/s/ George L. Hastings, Jr.
George L. Hastings, Jr.
Special Master

No. 19 -____

IN THE
Supreme Court of the United States

W.R. III, A MINOR, BY AND THROUGH HIS PARENTS AND NEXT FRIENDS, HEATHER ROGERO and WALTER ROGERO II,

Petitioner - Appellant,

v.

ALEX AZAR II,
SECY. OF HEALTH & HUMAN SERVICES
Respondent- Appellee.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

APPENDIX G
TO PETITION FOR A WRIT OF CERTIORARI
CONSTITUTIONAL PROVISIONS, STATUTES, AND REGULATORY PROVISIONS INVOLVED IN THIS CASE

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APPENDIX G

1. **U.S. Const. Amend. 14 provides:**
Requires the citizens not be denied "the *equal protection of the laws*" and "No person shall ...be deprived of life, liberty" "without" accurate and impartial procedural "due process of law" as does the later in U.S.C.A. Const. Amend. 5,

2. **The Rehabilitation Act of 1973, Section 504**, Pub. L. No. 93-112, 87 Stat. 394 (Sept. 26, 1973) is appropriate for the National Childhood Vaccine Injury Program;

> "No otherwise qualified individual with a disability in the United States, as defined in section 705(20) of this title, shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program [Vaccine Injury Compensation Program] or activity receiving Federal financial assistance or under any program or activity conducted by any federally funded program".

3. **42 U.S.C. §§ 300aa-1 to 300aa-34 et seq, The National Childhood Vaccine Injury Act of 1986 (NCVIA),** on a claim of vaccine-related encephalopathy injury causal from DTaP vaccine, under §300aa–11(c)(1)(C)(ii)(II), requiring preponderance standard:

42 U.S. Code § 300aa–10(a) PROGRAM ESTABLISHED
> There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a **vaccine-related injury** or death,

42 U.S. Code § 300aa–33(5) Encephalopathy is a Vaccine-Related Injury Associated with DTaP[3]

> **(5)** The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

42 U.S. Code § 300aa–11(c)(1). [Preponderance Standard of Each Factor Found Substantiated by Medical Opine or Medical Record, See Section 300aa–13]

§300aa-11(c) PETITION CONTENT A petition for compensation under the Program for a vaccine-related injury or death shall contain—

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[3] **Under 42 U.S. Code § 300aa–11(c)(1)(C)(ii)(II) "set forth in the Vaccine Injury Table** the first symptom or manifestation of the **onset** or significant aggravation of which **did not occur within the time period set forth in the Table** but which was **caused by** a vaccine referred to in subparagraph (A)"

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories, …

(C) [Two Statutory Sections for Encephalopathy "Set in the Table"]**

****(i)** ~~sustained, or had significantly aggravated, any illness, disability, injury, or condition~~ **~~set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph~~** ~~(A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death~~ ***~~occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or~~*** [irrelevant to *Rogero* claim]

~~**(ii)(I)** sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or~~ [irrelevant to *Rogero* claim]

*****(ii)(II)** sustained, or had significantly aggravated, any illness, disability, injury, or condition **set forth in the Vaccine Injury Table**[4] the first symptom or manifestation of the onset or significant aggravation of which ***did not occur within the time period set forth in the Table*** *but which was* ***caused by*** *a vaccine referred to in subparagraph* (A),

Encephalopathy under **§ 300aa–11(c)(ii)(II) requires medical opine *OR* medical record (preponderance) as defined by** Binding *Althen*: "The burden of a claimant under the National Childhood Vaccine Act is to show by preponderant evidence (medical opine or medical records) that the vaccination brought about her injury by providing:

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[4]42 CFR § 100.3 - Vaccine injury table.**(a)** In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa-14(c)), the following is a table of **vaccines, the injuries**, disabilities, illnesses, conditions, and deaths **resulting from the administration of such vaccines**"

II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, **DTaP**, P, DTP-Hib)	B. **Encephalopathy** or encephalitis

1. 45 CFR § 85.21 provides for VICP:

General prohibitions against discrimination.

(a) No [children with encephalopathy and autism] shall, on the basis of [autism], be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity conducted by the [HHS and HRSA for VICP].

(b) (1) The agency, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap -

(i) Deny a [children with encephalopathy and autism] the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a [children with encephalopathy and autism] an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a [children with encephalopathy and autism] benefit, or service [analysis] that is not as effective in affording equal opportunity to obtain the same result [compensation], to gain the same benefit, or to reach the same level of achievement as that provided to others;[94 other compensated children]

(iv) Provide different or separate aids, benefits, or services [an illegitimate definition of encephalopathy for causation analysis of autism or "neurodevelopmental disorder"] to individuals with handicaps or to any class or individuals with handicaps than is provided to others unless such action is necessary to provide qualified individuals with handicaps with aids, benefits or services that are as effective as those provided to others;

(vi) Otherwise limit a qualified individual with handicaps in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service.

(3) The agency may not, directly or through contractual or other arrangements, utilize criteria or methods of administration the purpose or effect of which would -

(i) Subject qualified individuals with handicaps to discrimination on the basis of handicap; or

(ii) Defeat or substantially impair accomplishment of the objectives of a program or activity with respect to individuals with handicaps. [to compensate vaccine-related encephalopathy]

(4)(i) Exclude individuals with handicaps from, deny them the benefits [compensation] of, or otherwise subject them to discrimination [in VICP] conducted by the [HRSA]; or

(ii) Defeat or substantially impair the accomplishment of the objectives of a program or activity with respect to individuals with handicaps. [Deny causation analysis on claim]

(5) The agency, in the selection of procurement contractors, may not use criteria that subject qualified individuals with handicaps to discrimination on the basis of handicap.

2. 45 CFR § 84.4 provides for VICP:

Discrimination prohibited.

(a)*General.* No qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any **program** or activity which receives Federal financial assistance.

(b)*Discriminatory actions prohibited.*

(1) A recipient, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, **on the basis of handicap**:

(i) Deny a qualified handicapped person the opportunity to participate in or **benefit from the aid, benefit**,...

(ii) Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or service to beneficiaries of the recipients program or activity; ...

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.

(2) For purposes of this part, aids, benefits, and services, to be equally effective, ... must afford handicapped persons equal opportunity to obtain the same result, to gain the same benefit, ...

(4) A recipient may not, directly or through contractual or other arrangements, utilize criteria or methods of administration (i) that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap, (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity with respect to handicapped persons, or (iii) that perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same State.

(5) In determining the site or location of a facility, an applicant for assistance or a recipient may not make selections (i) that have the effect of excluding handicapped persons from, denying them the benefits of, or otherwise subjecting them to discrimination under any program or activity that receives Federal financial assistance or (ii) that have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to handicapped persons.

(6) As used in this section, the aid, benefit, or service provided under a program or activity receiving Federal financial assistance includes any aid, benefit, or service provided in or through a facility that has been constructed, expanded, altered, leased or rented, or otherwise acquired, in whole or in part, with Federal financial assistance.

Evidence of Challenge/Rechallenge

1,2,3 DTaPs {see Dorsey's Ruling

uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: Cyanosis.

Gastrointestinal Disorders: Diarrhea, vomiting. – Diagnosed in hospital after 2nd DTaP - with 2 formed stools until age 4.5

General Disorders and Administration Site Conditions: Fatigue, injection site cellulitis, injection site induration, injection site itching, injection site nodule/lump, injection site reaction, injection site vesicles, injection site warmth, limb pain, limb swelling.

After 1st DTaP

Immune System Disorders: Anaphylactic reaction, anaphylactoid reaction, hypersensitivity.

Infections and Infestations: Upper respiratory tract infection. – After 1st DTaP - Xraup

Investigations: Abnormal liver function tests.

After 3rd+4th DTaP

Nervous System Disorders: Bulging fontanelle, depressed level of consciousness, encephalitis, hypotonia, hypotonic-hyporesponsive episode, lethargy, somnolence. after 4th "disoriented - all spheres" by MD

Psychiatric Disorders: Crying, insomnia, nervousness, restlessness, screaming, unusual crying.

diagnosed after 1st DTaP

Respiratory, Thoracic, and Mediastinal Disorders: Apnea, cough, dyspnea.

Skin and Subcutaneous Tissue Disorders: Angioedema, erythema, rash, urticaria.

Vascular Disorders: Pallor, petechiae.

4th DTaP confirmed by lot from GSK in Transcript as Infanrix

6.4 Postmarketing Spontaneous Reports for INFANRIX and/or ENGERIX-B

Worldwide voluntary reports of adverse events received for INFANRIX and/or ENGERIX-B in children younger than 7 years of age but not already reported for PEDIARIX are listed below. This list includes serious adverse events or events which have a suspected causal connection to components of INFANRIX and/or ENGERIX-B. Because these events are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Blood and Lymphatic System Disorders: Idiopathic thrombocytopenic purpura[a,b], lymphadenopathy[a], thrombocytopenia[a,b].

Gastrointestinal Disorders: Abdominal pain[b], intussusception[a,b], nausea[b].

General Disorders and Administration Site Conditions: Asthenia[b], malaise[b].

Hepatobiliary Disorders: Jaundice[b].

Immune System Disorders: Anaphylactic shock[a], serum sickness–like disease[b].

Musculoskeletal and Connective Tissue Disorders: Arthralgia[b], arthritis[b], muscular weakness[b], myalgia[b].

Claim injury

Nervous System Disorders: Encephalopathy, headache[a], meningitis[b], neuritis[b], neuropathy[b], paralysis[b]. – after 4th DTaP

Skin and Subcutaneous Tissue Disorders: Alopecia[b], erythema multiforme[b], lichen planus[b], pruritus[a,b], Stevens Johnson syndrome[a].

Vascular Disorders: Vasculitis[b].

★ encephalopathy manifesting with hypotonia is an allegation of case

[a] Following INFANRIX (licensed in the United States in 1997).

[b] Following ENGERIX-B (licensed in the United States in 1989).

★ are actual diagnoses in W.R. medical record

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Confirmed adverse effects

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vaccine (monovalent or as part of a combination vaccine), including vaccines from other manufacturers, in children born of HBsAg-negative mothers who are also scheduled to receive the other vaccine components of PEDIARIX.

A 3-dose series of PEDIARIX may be administered to infants born of HBsAg-negative mothers and who received a dose of hepatitis B vaccine at or shortly after birth. However, data are limited regarding the safety of PEDIARIX in such infants *[see Adverse Reactions (6.1)]*. There are no data to support the use of a 3-dose series of PEDIARIX in infants who have previously received more than one dose of hepatitis B vaccine.

Children Previously Vaccinated With Inactivated Poliovirus Vaccine (IPV):

PEDIARIX may be used to complete the first 3 doses of the IPV series in children who have received 1 or 2 doses of IPV from a different manufacturer and are also scheduled to receive the other vaccine components of PEDIARIX.

2.4 Booster Immunization Following PEDIARIX

Children who have received a 3-dose series with PEDIARIX should complete the DTaP and IPV series according to the recommended schedule.[1] Because the pertussis antigens contained in INFANRIX and KINRIX® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine), manufactured by GlaxoSmithKline, are the same as those in PEDIARIX, these children should receive INFANRIX as their fourth dose of DTaP and either INFANRIX or KINRIX as their fifth dose of DTaP, according to the respective prescribing information for these vaccines. KINRIX or another manufacturer's IPV may be used to complete the 4-dose IPV series according to the respective prescribing information.

3 DOSAGE FORMS AND STRENGTHS

PEDIARIX is a suspension for injection available in 0.5-mL single-dose vials and prefilled TIP-LOK® syringes.

Dr. Dalton wrote in record "severe eczemic eruption" + "severe skin allergies" after 1st DTaP.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

A severe allergic reaction (e.g., anaphylaxis) after a previous dose of any diphtheria toxoid-, tetanus toxoid-, pertussis antigen-, hepatitis B-, or poliovirus-containing vaccine or any component of this vaccine, including yeast, neomycin, and polymyxin B, is a contraindication to administration of PEDIARIX *[see Description (11)]*.

4.2 Encephalopathy

– Diagnosed by neurologist after regression of 4th DTaP

Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause is a contraindication to administration of any pertussis-containing vaccine, including PEDIARIX.

4.3 Progressive Neurologic Disorder

– became chronic after 6 mo & now permanent.

Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy is a contraindication to administration of any pertussis-containing vaccine, ~~including PEDIARIX~~. PEDIARIX should not be administered to individuals with such encephalopathy.