In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 02-472V
(To be published)

* *		
BRIAN HOOKER and MARCIE HOOKER, parents of SRH, a minor,	*	Filed: May 19, 2016
Petitioners,	*	
v.	*	Vaccine Act Entitlement; Causation-in-fact; Significant Aggravation; Thimerosal; Autism Spectrum Disorder; Mitochondrial Disorder
SECRETARY OF HEALTH AND HUMAN SERVICES	*	
Respondent.	*	
* *		

Clifford Shoemaker, Shoemaker, Gentry & Knickelbein, Vienna, VA, for Petitioners.
Justine Walters, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION

HASTINGS, *Special Master*.

This is an action in which Petitioners, Dr. Brian Hooker and Marcie Hooker, seek an award under the National Vaccine Injury Compensation Program (hereinafter "the Program"[1]), on account of their son SRH's autism spectrum disorder ("ASD"), which they assert to have been caused or aggravated by thimerosal-containing vaccinations administered to their son. For the reasons set forth below, I conclude that 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. Sec'y of Health & Human Servs.*, 527 Fed. App'x 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).

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.

I also note that while the Petitioners' *primary* contention throughout this case has been that vaccinations *initially caused* the autism spectrum disorder of SRH, late in the case they raised the alternative contention that SRH's vaccinations of May 26, 1999, *significantly aggravated* a pre-existing ASD, causing it to worsen. According to *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013), "the National Vaccine Injury Compensation Program *** allows certain petitioners to be compensated upon showing, among other things, that a person 'sustained, or had *significantly aggravated*' a vaccine-related 'illness, disability, injury, or condition.'" *Id*. at 1355-56, *quoting* 42 U.S.C. § 300aa-11(c)(1)(C)) (emphasis added.) In *Whitecotton v. HHS,* 81 F.3d 1099, 1103 (Fed. Cir. 1996), the U.S. Court of Appeals for the Federal Circuit stated that "the statutory requirements to make out a *prima facie* significant aggravation claim are analogous to those required to make out a *prima facie* initial onset claim." The Vaccine Act states that "[t]he term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health." § 300aa-33(4).

The elements of an off-Table *significant aggravation* case are set forth in *Loving v. HHS*, 86 Fed. Cl. 135, 144 (2009). There, the court combined the test from *Althen*, above, which defines off-Table causation cases, with the test from *Whitecotton v. HHS*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), which concerns on-Table significant aggravation cases. The resultant test has six components, which are:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C. v. HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims").

II

BACKGROUND: THE OMNIBUS AUTISM PROCEEDING ("OAP")

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

[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

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. 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).

(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).

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

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, 2012) (autism not caused by pneumococcal vaccination); *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); *Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *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); *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 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2015) (autism not caused by influenza vaccine) (not yet published), *aff'd* 2016 WL 552481 (Fed. Cl. J. Braden Feb. 12, 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); *Vernacchio v. HHS,* No. 08-504 (Fed. Cl. Spec. Mstr. Corcoran Feb. 19, 2016) (autism not caused by influenza

vaccine) (not yet published); *Murphy v. HHS*, No. 05-1063V, (Fed. Cl. Spec. Mstr. Corcoran April 25, 2016) (autism not caused by DTaP or MMR vaccines) (not yet published).

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). 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* (filed 4-18-16) (Judge Yock affirming).

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,

III

PROCEDURAL HISTORY OF THIS CASE

A. Petitioners' early efforts to present evidentiary support for their claim.

Petitioners filed a "Petition for Vaccine Compensation" on behalf of their son SRH on May 10, 2002. (ECF No. 1.) The Petition alleged that as the direct result of the MMR and Varivax vaccinations SRH received on February 25, 1999; the Hib (4th dose) vaccination he received on May 26, 1999; "and all the thimerosal containing vaccines" that he had received, SRH "developed Autism." (Petition, ¶¶ 7-8.) Further, Petitioners alleged that SRH's father "first noticed a change in [SRH's] behavior including loss of sparse language, loss of eye contact following the May 1999 vaccination." (*Id*., ¶9.)

On May 22, 2002, this case, along with many others, was stayed indefinitely pending completion of the general inquiry under the Omnibus Autism Proceeding regarding the possible causal relationship between certain vaccines and autistic spectrum disorders. (ECF No. 3.) (*See* Section II of this Decision above.)

Like all the cases stayed pending the OAP, this case was assigned to my docket, on July 29, 2002. (ECF No. 6.) On September 7, 2007, Petitioners filed medical records marked as Exhibits 1-15 (ECF No. 16), followed by Exhibit 16, filed on October 4, 2007 (ECF No. 17).

B. The (first) Amended Petition

Following the resolution of the autism "test cases" (see Section II above), Petitioners filed an Amended Petition ("Am. Pet.") on July 20, 2011, alleging that SRH developed "mercury poisoning" as a result of the MMR vaccination he received on February 25, 1999, and his fourth Hib vaccination, received on May 26, 1999. (Am. Pet., ECF No. 22, ¶¶ 7, 8, 15, 18.) (Although it is noteworthy that one of those two vaccinations, the MMR, in fact did *not contain* any mercury.) Petitioners alleged again that his father first noticed symptoms of SRH's developmental disorder "following the May 1999 vaccination." (*Id*., ¶ 9.)

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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.")

On August 15, 2011, I filed an Order directing Petitioners to file an expert report in support of their claim within 90 days, or a status report describing their efforts to provide an expert report. (ECF No. 24.) Over the course of the next fifteen months, Petitioners filed a series of seven status reports describing their efforts to contact potential experts who might be willing to opine about their claim. (ECF Nos. 25-31.)

On December 6, 2012, I filed an Order noting that fifteen months had passed, but Petitioners had not yet retained an expert. (ECF No. 32.) That Order warned Petitioners that if they failed to file an expert report within six months, their petition would be dismissed for failure to prove the case. (*Id*.)

C. Initial expert report of Dr. Mark Geier

Over the following six months, Petitioners filed three more status reports regarding their attempts to obtain the opinion of a medical expert. (ECF Nos. 33-35.) Then, on June 6, 2013, Petitioners filed the report of Dr. Mark Geier. (*See* Ex. 17, ECF No. 36-2.) A digitally-recorded status conference was convened, on June 20, 2013, at the request of Respondent, to discuss various aspects of Dr. Geier's report. (Order, filed June 27, 2013, ECF No. 39.) During that conference, Respondent noted that: 1) Dr. Geier's report was written in 2007, before the conclusion of the OAP test cases;[6] 2) Dr. Geier's report expounded theories that were rejected in the OAP test cases; and 3) that Dr. Geier's medical license had been revoked. (*Id*.)

On August 20, 2013, Respondent filed a Response to Petitioners' Expert Report and Motion to Dismiss this case, alleging that Dr. Mark Geier lacked appropriate qualifications to opine on this matter. (ECF No. 40, pp. 7-8.) Thereafter, Respondent filed Exhibits A and B, consisting of copies of official documents of the Maryland State Board of Physicians, which first suspended, then revoked the medical license of Dr. Mark Geier, effective as of August 22, 2012. (ECF No. 41, filed Sep. 4, 2013.)

D. Petitioners' additional expert reports

Petitioners on October 4, 2013, filed a response to Respondent's Motion to Dismiss. (ECF No. 43.) Petitioners also on October 4, 2013, filed Exs. 19 and 20. (ECF No. 44.) Ex. 19 included of a 69-page declaration of Brian Hooker, one of the Petitioners in this case. That filing elaborates Dr. Hooker's criticisms of evidence presented by Respondent during the OAP litigation, his defense of the qualifications of Dr. Geier, and various assertions of improper conduct by Respondent. The balance of Ex. 19 consisted of 276 pages of various materials that Dr. Hooker cites in his critique. Ex. 20 consisted of a resume of Brian Hooker.

Also on October 4, 2013, Petitioners filed five expert reports. (ECF Nos. 45, 46.) These reports included: Ex. 21, the report of David Geier; Ex. 23, the supplemental report of Dr. Mark Geier; Ex. 25, the report of Janet Kern, Ph.D.; Ex. 27, the report of Boyd Haley, Ph.D.; and Ex. 29, the report of Stephen Smith, M.D., one of SRH's treating physicians. (*Id*.) On October 8,

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[6] Petitioners' Ex. 17, signed by Dr. Geier, was dated Nov. 11, 2007; that is, about 5½ years before it was filed, on June 6, 2013. (*See* Ex. 17, p. 11.)

2013, Petitioners filed Ex. 30, a revised version of Dr. Kern's previous expert report. (ECF No. 49.)

A digitally-recorded status conference convened on November 15, 2013, during which I denied Respondent's Motion to Dismiss. (Order, ECF No. 52, filed Nov. 20, 2013.) At that conference, the parties also discussed the possible filing by Petitioners of another expert report, to be prepared by Dr. Frances Kendall. Petitioners were allowed additional time to file that report. (*Id*.) Petitioners subsequently filed a series of motions, each requesting additional time to file such report, and those motions were granted. (*See* ECF Nos. 53, 55, 56, 57.) However, on the ultimate due date for Dr. Kendall's report, Petitioners instead filed the expert report of Mary Megson, M.D. (*See* Ex. 32, ECF No. 58-2, filed April 18, 2014.) Respondent was allowed 60 days to file responsive expert reports. (ECF No. 59.)

On April 22, 2014, Respondent moved to amend the procedural schedule, in order to postpone the filing of Respondent's "Rule 4 report" and expert report, until Petitioners submitted multiple medical records. (ECF No. 60.) Accordingly, on April 28, 2014, I filed an Order to amend the schedule, which required Petitioners 1) to complete the medical records, 2) to clarify whether more expert reports would be filed, and 3) to specify which of the already-filed expert reports would be relied on by Petitioners. (ECF No. 61.) In response, Petitioners filed medical records on various dates, designated as Exhibits 34 through 48, and 50 through 57 (*see* ECF Nos. 62, 63, 66, 68-70, 73, and 76), and a statement that the medical record was complete (ECF No. 74.) Petitioners also filed a status report, dated May 28, 2014, indicating that they did not anticipate filing any more expert reports. (ECF No. 64.)[7]

E. Respondent's Report and (second) Motion to Dismiss

On January 22, 2015, Respondent filed the reports of three medical experts,[8] along with medical literature. (ECF No. 83.) On that same date, Respondent filed a second Motion to Dismiss, and Respondent's "Rule 4 report,"[9] stating Respondent's position that Petitioners' claim should be denied. (ECF No. 82.)

The Motion to Dismiss was based on Respondent's defense that the original Petition in the case was untimely filed. (*See* ECF No. 82, pp. 18-21.) Respondent argued that the first symptoms of SRH's condition -- that is, autism -- appeared before May 10, 1999, which was three years before the filing date of this petition. (*Id*.) Thus, Respondent contended that Petitioners failed to comply with the Vaccine Act's statute of limitations, which requires that a

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[7] During June through August of 2015, Petitioners also filed Exhibits 58-59, 61, and 63-88, which were identified as medical literature. (ECF Nos. 93, 105, 113-15.)

[8] *See* Ex. C, the report of Bennett Leventhal, M.D.; Ex. F, the report of Edward Cetaruk, M.D.; and Ex. H, the report of Gerald Raymond, M.D.

[9] That report was labelled as a "supplemental" report, but was actually the only "Rule 4 report" that Respondent filed in this case.

petition must be filed within 36 months of the date when the symptoms of an alleged vaccine-related injury first occurred.[10] (*Id*.)

F. Allegation of "significant aggravation" in Petitioners' Second Amended Petition

On March 9, 2015, Petitioners filed a Second Amended Petition ("2nd Am. Pet."), which again alleged that SRH developed "mercury poisoning" as the direct result of the MMR vaccination that he received on February 25, 1999, and the Hib vaccination he received on May 26, 1999. (2nd Am. Pet., ¶¶ 7, 8, 20.) Petitioners once again alleged that they first noticed symptoms of SRH's condition "following the May 1999 vaccination." (*Id*., ¶ 9.)

This Second Amended Petition, however, also added an alternative pleading that "the vaccinations that [SRH] received within the three years prior to filing the Petition significantly aggravated his autism." (2nd Am. Pet., ¶18.) They followed that up with a document filed on March 23, 2015, which stated that the vaccinations which allegedly caused the "significant aggravation" were "the vaccinations that he received on May 26, 1999." (ECF No. 95, p. 18.)

On March 17, 2015, a status conference was held, to address the "significant modifications of petitioners' theory of this case," namely their addition of the alternative significant aggravation theory. (Order, filed March 18, 2015, ECF No. 92.) As a result of that discussion, Petitioners were instructed to file "supplemental expert reports from any of petitioners' experts who will participate in the trial of this case, explaining why they support the theory stated in the [Second] Amended Petition." (*Id*.) The above-cited language in the Order filed on March 18, 2015, contained an implicit warning that *only* those experts who filed supplemental reports supporting Petitioners' most recent allegations in the Second Amended Petition would be welcome to testify at any evidentiary hearing, or considered in resolving the case.

On March 26, 2015, I filed another procedural Order, which included the following language:

> Due to the [Second] Amended Petition filed on March 9, 2015, and the theory contained therein that S.R.H.'s injury was aggravated by vaccinations given on February 25 and May 26, 1999, I will not rule on Respondent's timeliness motion at this time.

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[10] A document titled "Respondent's Response to Petitioners' Allegations of Misconduct and Motion to Strike," was also filed on January 22, 2015. (ECF No. 81.) This filing presented arguments that various paragraphs within Petitioners' Exhibit 19, the affidavit of Brian Hooker, should be stricken from the record because they contain, *inter alia*, baseless accusations that attorneys of the U.S. Department of Justice committed misconduct. (*Id*.) On April 7, 2015, Petitioners filed a Response to that Motion to Strike. (ECF No. 101.) Although I found no reason to conclude that any of Respondent's attorneys had committed misconduct, I did not strike any of Ex. 19 from the record.

> I note that due to my Order filed on March 18, 2015, Petitioners' supplemental expert reports are due on May 18, 2015.

(ECF No. 97.)

Petitioners asked for an enlargement of time to provide the medical records requested in my Order, dated March 18, 2015. (ECF No. 103, filed May 1, 2015.) I granted Petitioners' Motion, but included a specific reminder that "their expert reports are still due on May 18, 2015." (Order, filed May 1, 2015, ECF No. 104.)

G. Filings since May of 2015

On May 18, 2015, Petitioners filed a Status Report. (ECF No. 107.) That status report stated:

> Petitioner has discussed the reports filed by all the experts in this case with the experts for the Petitioner, and *Petitioner does not feel that any further supplemental reports are necessary*. Petitioner is ready to schedule this case for a hearing.
>
> Both Dr. Smith and Dr. Megson have indicated that the vaccines administered on May 26, 1999 (DTaP, OPV, and Hib) triggered the onset of SRH's encephalopathy resulting in autism. If the court determines that there were earlier symptoms of "autism", something which Petitioners absolutely do not agree with, then it is clear from the medical records that his condition dramatically changed for the worse after the May 26, 1999 vaccinations, and the opinions of Drs. Megson and Smith would be that this dramatic change was triggered, as they have stated, by these 15 month vaccinations.

(ECF No. 107) (emphasis added.) Thus, my Order of March 18, 2015 -- that Petitioners provide *supplemental expert reports*, clarifying whether any of Petitioners' experts supported the "significant aggravation" allegations of their *Second Amended Petition* -- was not satisfied.

Accordingly, on May 20, 2015, I filed an Order commenting on Petitioners' failure to provide supplemental expert reports in support of the new theory presented in Petitioners' Second Amended Petition. (ECF No. 109.) I noted that, contrary to my specific direction, Petitioners had expressly declined to file any supplemental expert reports to support their new alternative theory of significant aggravation, preferring instead to rely on the previously submitted expert reports of Dr. Smith and Dr. Megson. (*Id*.) Considering these factors, I determined that the appropriate procedure to resolve this case would be to *rule on the existing written record*, without an evidentiary hearing, pursuant to Vaccine Rule 8(d). (*Id*.)

Petitioners have *not objected* to the procedure outlined in my Order filed on May 20, 2015, or even commented on it. Petitioners have had ample opportunity since then, to file a request for an evidentiary hearing or some other procedure, but they have not done so.

On June 30, July 21, and August 3 of 2015, Petitioners filed Exhibits 63 through 88, which are identified as "medical literature." (ECF Nos. 113 – 115.) My review of these exhibits does not reveal any explanation regarding the relevance of this material, or how any particular article might offer support for Petitioners' contentions.

IV

FACTS

A. Medical records concerning SRH's first year of life

Petitioners' son, SRH, was born on February 10, 1998. (Ex. 10, filed Sept. 7, 2007, p. 87.)[11] SRH received routine post-natal care, then regular examinations performed by pediatrician Dr. Heller-Bair, through his early years of life. (Ex. 35, ECF No. 62-3, pp. 2-11.) In his first year, SRH experienced a number of unremarkable illnesses, especially ear infections. (*Id*.) He also received the typically recommended pediatric vaccinations.[12]

During SRH's early months, using the Denver II Developmental Screening Test ("DDST"), Dr. Heller-Bair frequently recorded SRH's developmental progress. (Ex. 35, pp. 4, 5, 8, 11, 13, 24.) This screening tool allows medical personnel to indicate a "pass" ("P") or "fail" ("F") for each infant milestone, on a chart divided into age groups. At four months of age, Dr. Heller-Bair noted "fail" for three developmental milestones that SRH had not achieved. (Ex. 35, p. 24.) At six months of age, there are again notations indicating that SRH failed to achieve three milestones. (*Id*.) At nine months, he failed two milestones, as he was not using "mama/dada" and could not sit up alone. (*Id*.) At his twelve-month check-up, on February 25, 1999, he could only speak two words, and was not yet able to drink from a cup. (*Id*.)

B. Medical records relating to period between 12 months and 15 months of age

At one year of age, on February 25, 1999, SRH was assessed as "healthy," although his parents were still concerned that he sometimes tugged at his ears. (Ex. 35, p. 11.) SRH received MMR and varicella vaccinations during this office visit. (*Id*., p. 26.) He returned to the pediatrician's office about three weeks later, on March 22, with a low-grade fever lasting three days, and a resurgence of ear infection (otitis media). (*Id*. p. 11.) During March through May, SRH continued to experience recurrent problems with upper respiratory infections and ear infections. (*Id*., pp. 10-13.)

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[11] Petitioners, on Sept. 7, 2007, filed a Notice of the pending filing of Exhibits 1-15 (ECF No. 16), and the compact disc containing those exhibits was received on September 13. These exhibits are not accessible on the electronic docket, and are contained in the record of this case on the compact disc.

[12] On 2/24/98, he received Hep B #1; on 4/9/98 -- DTaP #1, IPV #1, Hib #1, and Hep B #2; on 6/10/98 -- DTaP #2, IPV #2, and Hib #2; on 8/20/98 -- DTP #3, Hib #3, and Hep B #3; on 2/25/99 -- MMR and Varivax. (Ex. 35, p. 26.)

Dr. Randall Fong, an otolaryngologist, evaluated SRH's hearing on March 30, 1999, because of his persistent ear infections, and his parents noted that he was "very sensitive to noises." (Ex. 35, pp. 45-46.) Upon examination, Dr. Fong concluded that SRH had "[M]ild hearing loss likely conductive in nature," and also "[h]ypersensitivity to sound of unknown etiology." (*Id*.) He recommended the placement of bilateral myringotomy tubes in one month, if SRH's middle ear effusions did not resolve. (*Id*.)

C. Medical records concerning period between 15 and 18 months of age

SRH received his 15-month well child examination on May 26, 1999, and was found to be "healthy." (Ex. 35, p. 13.) However, at this visit his developmental progress chart indicates that SRH had not achieved most of the expected milestones. (*Id*., p. 24.) His Denver II developmental progress chart indicates that he could not speak six words, could not run or climb stairs, could not remove garments or use a spoon, and could not stack two cubes, -- indeed, he failed all but one of the developmental milestones for 15 months. (*Id.*) Following a physical examination of SRH, Dr. Heller-Bair administered the usually recommended vaccinations -- *i.e.,* DTaP #4, Hib #4, and OPV. (*Id*., pp. 13, 26.) (These vaccinations of May 26, 1999, were the vaccinations that Petitioners now allege to have "significantly aggravated" SRH's autism.)

Nineteen days later, on June 14, 1999, both parents accompanied SRH to the pediatrician's office, where she recorded that his temperature was 101.8°, and that both tympanic membranes appeared normal. (Ex. 35, p. 14.) She included the following description.

> One-year-old with 1-day history of low-grade fever, irritability, decreased appetite, nasal congestion. Child has a history of recurrent ear infections. Is scheduled for typanostomy tube placement by Dr. Fong in about 4 days' time. Mom is concerned that he may have an ongoing ear infection prior to surgery.

(*Id*.) No other recent symptoms were noted. Dr. Heller-Bair determined that SRH had a viral upper respiratory infection -- in other words, "a cold" -- and reassured the parents that he did not have an ear infection. (*Id*.)

On June 16, Dr. Fong reexamined SRH and noted "Viral illness, appears to be recovering and is not having the fevers." (Ex. 7, p. 5.) On June 18, 1999, he performed surgery to place SRH's tympanostomy tubes. (Ex. 10, pp. 103-21.) Dr. Fong reevaluated SRH on June 30, 1999, and found the tympanostomy tubes were in place and functioning, with "[n]o middle ear effusion or fluid in the external auditory canal." (Ex. 7, p. 6.) Audiometric testing of SRH showed "improvement of his hearing in the near normal ranges," while his chronic otitis media with effusion was characterized as "resolved." (*Id*.)

D. Recognition of SRH's early symptoms of autism

There were no office visits or recorded medical observations in July and most of August, 1999. On August 30, 1999, Dr. Heller-Bair performed an eighteen-month well-child check on SRH, and assessed him as generally "healthy," but suffering from an upper respiratory infection. (Ex. 35, p. 14.) During this visit, SRH's DDST chart indicates that he was still unable to stack cubes or run, but his vocabulary had increased to six words. (*Id*., p. 24.) Further, SRH exhibited decreased cooperation and less responsiveness to his name, but increased concentration on his "own world." (*Id*., p. 14.) Dr. Heller-Bair noted her concern about "slow development," and

referred him for further developmental testing. (*Id.*) That referral specifically requested an evaluation "for autism as well." (*Id*. p. 15.) On September 8, 1999, a member of the doctor's staff noted a telephone discussion with SRH's mother, and mentioned that she had been "very upset" with the doctor about the scheduled autism test, but she was "OK now." (*Id*.) Appointments for developmental testing by Ramona Grimm, and autism testing by Dr. Sierra, were scheduled. (*Id*.)

On September 14, 1999, Sara Zirkle, M.D., performed an evaluation of SRH because his parents were "very concerned about his rate of development." (Ex. 6, p. 7.) Dr. Zirkle recorded his mother's statement that SRH had "always been a large child*** and his head had always been a bit big." (*Id*.) The parents reported that: "He was slow to walk but their primary concerns are in the area of communication. He does not wave bye-bye. He has about a ten-word vocabulary." (*Id*.) A questionnaire filled out by his parents during that visit indicates that SRH had not been waving "bye-bye" for about six months. (*Id*., p. 19.) They also reported that SRH had a four to six-word vocabulary at sixteen months (in May 1999), and seven to ten words at eighteen months (in August 1999). (*Id*., p. 17.)

Dr. Zirkle observed several other characteristics of SRH, such as hand-flapping, failing to respond to his name, and inability to indicate his needs by pointing. (Ex. 6, p. 7.) Her impression of SRH was "[s]uspect mild developmental language disorder." (*Id*.) Two days later, on September 16, Dr. Zirkle noted that SRH's head size was "out of proportion with height and weight and growing faster than normal growth rate (he did have an ultrasound of his head at age 1 year, which showed no hydrocephalus)." (*Id*.) She then restated her general impression that SRH exhibited "[d]evelopmental delay primarily in language in a child who is excessively large for his age with his head being out of proportion to body." (*Id*.) She recommended chromosome studies to learn if he had Fragile X syndrome. (*Id*.)

On October 7 through 15, 1999, when SRH was twenty months old, specialists at the Benton-Franklin Developmental Center administered several tests to SRH. (*See* Ex. 1.) Marie Holst, a special education teacher, noted that he was "functioning within normal limits in the personal/social, adaptive, and cognitive areas." (Ex. 1, p. 3.) However, his gross motor function registered at only 70% of proficiency, and an attempt to assess his fine motor ability was unsuccessful. (*Id.*, p. 4.) His speech and language assessment showed receptive language at only 20% proficiency (equivalent to 4 months of age), while his expressive language registered at 40% of proficiency (equivalent to 8 months of age). (Ex. 1, pp. 11-12.) Based on this evaluation, SRH was enrolled to receive a variety of therapies. (*Id*., p. 27.) SRH began receiving speech therapy, along with physical and behavioral training at this time. (*See e.g.*, Ex. 1; Ex. 35, p. 15; Ex. 6, pp.7-8.)

Dr. Zirkle reexamined SRH on October 11, 1999, and reported to his parents the results of the genetic tests, which had not revealed Fragile X or any other abnormality. (Ex. 6, pp. 8, 11-12.) She noted her current impression: "Developmental delay in speech and language." (*Id*., p. 8.)

During November/December 1999, and January 2000, SRH's parents brought him to their pediatrician's office on several occasions, with complaints related to otitis media, teething, enlarged tonsils, cough, fever, and runny nose. (Ex. 35, pp. 16-17.) On each occasion, he received treatment for the condition indicated, without further developmental assessment. (*Id*.)

On January 25, 2000, Dr. Zirkle reexamined SRH and noted his father's report that "there are some things that he used to do that he will not do now," such as using certain words and gestures. (Ex. 6, p. 8.) She also discussed a sensory integration treatment program (AYRES) that the parents wished to implement. (*Id*.)

E. Medical treatment by Dr. Stephen Smith

Petitioners began taking SRH to Stephen Smith, M.D., on August 1, 2000. (Ex. 5, pp. 30-31.) (But see negative information concerning Dr. Smith at Section IX(A), below.) Dr. Smith noted that SRH was a two-year-old with developmental delay, and that "[e]ye contact is not good, but there is some contact with both of his parents." (*Id*.) He noted SRH's history of "diarrhea now and in the past, learning disabilities, ear infections," and the presence of tympanostomy tubes. His initial assessment included: "pervasive developmental delay" (a form of ASD), and "toxic encephalopathy." (*Id*.) Dr. Smith scheduled numerous laboratory tests and initiated various dietary supplements and "mercury detoxification." (*Id*.)

It appears that Dr. Smith continued to provide medical services for SRH at least through August 2007. (*See* Ex. 5, pp. 6-31; Ex. 14, pp. 1-47.) Throughout that period, Dr. Smith repeated the "toxic encephalopathy" diagnosis for SRH. (*See generally* Ex. 14.) During his approximately seven years of providing medical services, Dr. Smith collected a multitude of blood, hair, urine, and fecal samples from SRH and submitted them for laboratory analyses. (*See* Ex. 5, pp. 32-162; Ex. 14, pp. 48-322.) He also prescribed numerous nutritional supplements and pharmaceuticals. (*Id*.)

F. Confirmation of SRH's autism diagnosis

On December 4, 2000, SRH's mother brought him twice to the office of Dr. Heller-Bair, because he had suffered from diarrhea and vomiting for several days. (Ex. 35, p. 20.) He was diagnosed with gastroenteritis, and his mother was instructed to "force clear liquids" to counter dehydration. (*Id*.) After the second visit, he was sent to Kennewick General Hospital to receive intravenous fluids. (Ex. 3, pp. 7-8.) At the hospital, his past medical history noted "[d]evelopmental delay with probable infantile autism." (*Id*.) His "speech was zero." (*Id*.) His diagnoses were gastroenteritis and dehydration. (*Id.*)

Also on December 4, 2000, an unidentified person filed a report with the Vaccine Adverse Event Reporting System ("VAERS") alleging that SRH had suffered a reaction to vaccines. (Ex. 50.) That report states that SRH had suffered an adverse response to the three vaccines that he received on May 26, 1999 (that is, DTaP, Hib, OPV). (*Id*., p. 1.) The "date of onset" of the adverse reaction is identified as August 1, 1999 (that is, 67 days after his vaccinations). (*Id.*) The adverse event is described as:

> Loss of verbal communication, gradual reversal of words (verbalization) achieved by 18 months of age. Medical impressions of developmental delay, communication delays (speech). Gross motor delays. Mercury toxicity. RX: participation in Early Childhood Development Therapy, Speech, Physical and Children's Center. C/O sensory and developmental delays-verbal.

(*Id.*)[13]

On January 19, 2001, Michaele Tahvili, a psychologist for the local school district, evaluated SRH, and commented that "[A]utism is major concern voiced by parents." (Ex. 2, p. 64.) Further, she noted that "[p]arents suspect that [SRH's] autistic behavior may be related to mercury poisoning. *** Diagnosed with mercury poisoning 11-28-00 by Dr. Stephen Smith." (*Id*.) On February 5, 2001, Ms. Tahvili reported that "the comprehensive evaluation we have done here at Keewaydin Discovery Center indicates that [SRH] has autism." (Ex. 2, p. 73.)

V

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

Both parties in this case have consulted several medical experts. Petitioners filed the expert reports of Mark Geier, M.D. (Exs. 17, 23); David Geier (Ex. 21); Janet Kern, Ph.D (Exs. 25, 30); Boyd Haley, Ph.D (Ex. 27); Stephen Smith, M.D. (Ex. 29); and Mary Megson, M.D. (Ex. 32). Respondent filed the expert reports of Bennett Leventhal, M.D. (Ex. C); Edward Cetaruk, M.D. (Ex. F); and Gerald Raymond, M.D. (Ex. H).

Petitioners filed all of their expert reports on or before April 18, 2014. Eleven months later, on March 9, 2015, Petitioners filed their Second Amended Petition (ECF No. 90), which substantially changed their theory of vaccine causation by adding a new alternative allegation of "significant aggravation." (*Id.*) On March 18, 2015, Petitioners were ordered to file supplemental reports wherein their experts would explain their support for the change presented in the Second Amended Petition. (ECF No. 92.) Petitioners declined to do so, asserting that "further supplemental reports" were not necessary. (Status Report, filed May 18, 2015, ECF No. 107.) Petitioners' most recent explanation of their theory of causation emphasizes their reliance on the opinions of Dr. Stephen Smith and Dr. Mary Megson. (*Id*.)

In this section, I will summarize the qualifications and the opinions of all of the experts, both for Petitioners and for Respondent. However, given Petitioners' emphasis on the opinions of Dr. Smith and Dr. Megson, as alleged proponents of their revised theory, I will pay particular attention to those two experts.

A. Petitioners' experts

As noted above, in their Status Report filed on May 18, 2015, Petitioners seemed to indicate that in support of their latest theory of causation, stated in their Second Amended Petition, they were relying on the testimony of Dr. Smith and Dr. Megson. (ECF No. 107.) They did *not*

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[13] A few weeks after the VAERS report was filed, Dr. Hooker signed a VAERS "Authorization for Release of Information" on Jan. 6, 2001. (Ex. 14, p. 319.) It is notable that Dr. Hooker altered this pre-printed VAERS "release" form. Dr. Hooker inserted the words "and before" between "on" and "5/26/99" on the form. (*Id.*) To further clarify his meaning, he wrote in the margin "(vaccines on and before 5/26/99)." (*Id.*) In this document, thus, Dr. Hooker seemed to indicate his belief that SRH's condition was caused by a *series* of vaccinations that he received, up to and including May 26, 1999.

mention any of the other experts whose reports they had filed previously. (*Id.*) Accordingly, I will begin my discussion of Petitioners' experts with Dr. Smith and Dr. Megson.

1. Petitioners' first primary expert, Stephen L. Smith, M.D.

a. Qualifications

The qualifications of Petitioners' expert, Dr. Smith, have not been described in great detail in the record of this case. No *curriculum vitae* or list of his credentials has been filed. However, some facts can be gleaned from the record, both from Dr. Smith's expert report itself and from certain disciplinary documents concerning Dr. Smith put into the record by Respondent. [14]

Dr. Smith graduated from medical school in 1980, and received a license to practice as a physician and surgeon in the State of Washington, in June 1981. (Ex. J, p. 6, ¶¶ 1.1, 1.2.) He worked at an urgent care facility for one year, before opening his own urgent care center in 1982. (*Id*., ¶ 1.2.) Dr. Smith did not complete a formal residency program, but he received additional medical training, primarily in alternative medicine, by attending seminars. (*Id*.) He is not board-certified in any specialty. (Ex. K, p. 2, ¶ 2.1.)

Dr. Smith maintains his own practice of "integrative medicine," at Northwest Integrative Medicine, in Pasco, Washington. (Ex. K, p. 2, ¶ 2.1.) He has stated in his expert report that he specializes in chronic diseases such as autism, fibromyalgia, and autoimmune disorders, representing that he has been treating autistic children with developmental delays for over twenty years. (Ex. 29, ECF No. 46-6, p. 1.)

Dr. Smith provided medical treatment for SRH for several years, beginning in August 2000.[15]

The documents placed into the record by Respondent, however, indicate that Dr. Smith has twice been disciplined by his state medical society, for irresponsible treatment of two young patients whom, like SRH, he had diagnosed to be suffering from "mercury toxicity." In one case, the disciplinary board concluded that there was no evidence to support Dr. Smith's diagnosis. (These disciplinary actions will be described in greater detail below, in Section IX(a) of this Decision.)

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[14] Respondent filed Exhibits J and K, on January 22, 2015. (ECF Nos. 83-8, 83-9.) These exhibits are copies of documents which describe certain disciplinary actions taken by the Department of Health of the State of Washington against Dr. Smith, in 2007 and 2014.

[15] The medical notes concerning care provided for SRH by Dr. Smith, between August 2000 and August 2004, are located at Ex. 5, pp. 6-31. Additional notes for more recent dates are in Ex. 14.

b. Summary of Dr. Smith's opinion

Petitioners filed the expert opinion of Dr. Smith on October 4, 2013. (Ex. 29, ECF No. 46-6.) In that report, Dr. Smith stated that certain children have "genetic weaknesses that predisposes them to injury." (*Id*., p. 1.) Dr. Smith opined that in such vulnerable individuals the mercury contained in "thimerosal," a preservative included in certain vaccines, can cause "neurological injury leading to severe developmental delays (speech and language delays) with features of autism spectrum disorder." (*Id*.) Dr. Smith stated that SRH was "particularly vulnerable" to the mercury contained in his vaccines, "due to the combination of various genetic anomalies he possesses." (*Id*.) Dr. Smith opined that SRH's vaccinations when he was fifteen months old "acted as a trigger for the series of events that led to his disability." (*Id*., p. 2.) The primary factor that led Dr. Smith to this conclusion was the allegedly strong temporal relationship between those vaccinations and the alleged onset of SRH's "regression" within the following two weeks. (*Id*., pp. 1-2.)

2. Petitioners' second primary expert, Mary N. Megson, M.D.

a. Qualifications

Dr. Mary Megson, M.D., graduated *cum laude* in 1974 from Hollins College with a Bachelor of Science degree. She earned her medical degree from The University of Virginia School of Medicine in 1978. She interned and completed her residency at the Boston Floating Hospital at Tufts Medical Center. She completed a fellowship in Ambulatory Pediatrics at Boston Children's Hospital, as well as a fellowship in Child Development at the Medical College of Virginia. (Ex. 33.)

Dr. Megson served as a clinical instructor in pediatrics from 1982 to 1984, at the Bowman Gray School of Medicine. During that same time period, she provided care for HMO patients participating in the Winston-Salem Health Care Plan, Inc. From 1984 to 1988 she participated in two different private medical practices. From 1988 to 1990, she served in a fellowship at the Medical College of Virginia. (Ex. 33.)

Dr. Megson is certified by the American Board of Pediatrics. Between 1990 and 1999, she served as Director of Developmental Pediatrics at the Children's Hospital in Richmond, Virginia. From 1997 to 1999, she was also an Assistant Clinical Professor of Pediatrics at the Medical College of Virginia. From 1999 to 2001, she served as an Associate Clinical Professor of Pediatrics at the same medical school. (Ex. 33.)

Since 1999, Dr. Megson has maintained her own private pediatric medical practice in Richmond, Virginia. (Ex. 33.)

b. Summary of Dr. Megson's opinion

On April 18, 2014, Petitioners filed an expert report of Dr. Megson, designated as Ex. 32 (ECF No. 58-2). In her report, Dr. Megson reviewed SRH's medical records, noting that Dr. Smith had diagnosed SRH with "mercury poisoning" on November 28, 2000. (Ex. 32, p. 6 of 12.) She also noted Dr. Smith's diagnosis in 2003, that SRH "has an autism spectrum disorder." (*Id*., p. 8.) Dr. Megson reported that laboratory tests, prescribed by Dr. Smith in 2003, indicated that SRH had alleged immunologic irregularities. (*Id*., pp. 8-9.)

Dr. Megson also discussed the numerous laboratory tests ordered by Dr. Geier in 2007, when he diagnosed SRH with "autistic disorder" and "toxic encephalopathy." (Ex. 32, p. 9.) She noted that Dr. Geier performed genetic testing, and apparently accepted Dr. Geier's analysis of such genetic tests, along with his conclusion that, because of these genetic abnormalities, SRH "is more susceptible [to] oxidative stress due to environmental toxins including mercury." (*Id*.)

In her summary of SRH's medical history, Dr. Megson emphasized his *cumulative* exposure to mercury on account of his thimerosal-containing vaccines. (Ex. 32, pp. 2, 10.) She stated that, "[t]himerosal in vaccines administered on February 29, 1998; April 9, 1998; June 10, 1998 and August 20, 1998 caused and progressively exacerbated an underlying mitochondrial disorder."[16] (*Id*., p. 10.) Based on her review of the medical records, Dr. Megson stated that SRH "started to regress after 15 months" of age. (*Id*., p. 2.)

Dr. Megson concluded that for SRH, "thimerosal containing vaccines caused and exacerbated an underlying mitochondrial dysfunction." (Ex. 32, p. 12.) Then, "the combination of vaccines and otitis media at age 15 months led to a prolonged fever which conspired with the mitochondrial disorder, manifesting in chronic inflammation and regressive encephalopathy." (*Id*.)

3. Petitioners' expert, Dr. Mark Geier

a. Qualifications

Dr. Mark Geier received a Bachelor of Science degree in 1970, and a Ph.D. in genetics in 1973, both from George Washington University in Washington, DC. In 1978 he completed a medical degree at the same university. He performed an internship in Obstetrics and Gynecology at Johns Hopkins Hospital in Baltimore during 1978-79, then served as an Assistant Professor of Gynecology and Obstetrics at the Johns Hopkins School of Medicine in 1979-82. He also worked as an Assistant Research Professor at the Psychiatry Department of the Uniformed School of the Health Sciences in Bethesda, MD, in 1981-1984. (Ex. 24, ECF No. 45-5, pp. 1-2.)

From 1988 through 1994, Dr. Geier was Director of the Maryland Medical Laboratory, Inc., in Baltimore. From 1997 through the present, he has been President of both the Genetic Counseling and Research, Inc., and the Genetic Centers of America, in Baltimore. Dr. Geier has been certified by the American Board of Forensic Examiners and the American Board of Forensic Medicine. (Ex. 24, pp. 2-3.)

As will be detailed, below however, Dr. Geier has been subject to extreme criticism as an expert witness, and his treatment and diagnosis of ASD patients has led to revocation of his license to practice medicine. (See Section IX(B) of this Decision, below.)

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[16] Mitochondria are microscopic structures within human cells that generate energy. (DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (31st ed. 2007), p. 1187.)

b. Summary of Dr. Geier's opinions

As noted above, the first expert opinion filed in this case was authored by Dr. Geier, and filed as Exhibit 17 (ECF No. 36-2), on June 6, 2013. In Ex. 17, he reviewed SRH's medical history based on interviews with SRH's parents and his own medical examination of the child -- both the interviews and examination were performed in 2007. (Ex. 17, p. 1 of 11.)[17] He also relied on *some* of SRH's prior medical records, as listed in the report. (*Id*. pp. 3-10.) Dr. Geier concluded that SRH had clinical symptoms consistent with "autistic disorder." (*Id*., p. 11.) He opined that SRH's condition was "the apparent result of a toxic encephalopathy" that was "significantly contributed to by mercury exposure." (*Id*.) Further, SRH's exposure to mercury was from thimerosal-containing vaccines and other environmental sources. (*Id.*)

In a supplementary opinion, Exhibit 23, filed on October 4, 2013, Dr. Geier presented his *general* theory that exposure to "[t]himerosal-containing childhood vaccines" can cause or significantly contribute to the development of ASD. (Ex. 23, p. 1, ECF No. 45-4, filed Oct. 4, 2013.)

4. Petitioners' expert, Mr. David Geier

On October 4, 2013, along with the supplemental expert report of Dr. Mark Geier, Petitioners also filed a report by Dr. Geier's son, Mr. David Geier, as Ex. 21. (ECF No. 45-2.) That report did not state an opinion specific to the case of SRH, but opined generally that thimerosal can cause or contribute to causing an ASD. (Ex. 21.)

However, special masters in prior Program cases have noted that David Geier lacks any qualifications to provide expert opinion on medical matters, his only degree being a Bachelor of Arts degree with a major in biology. *E.g., Riggins v. HHS*, No. 99-382V, 2009 WL 3319818, at *6-7 (Fed. Cl. Spec. Mstr. June 15, 2009); *King v. HHS*, No. 03-584V, 2010 WL 5470787, at *20 (Fed. Cl. Spec. Mstr. Dec. 13, 2010).

5. Petitioners' expert, Janet Kern, Ph.D.

a. Qualifications

Janet Kern received an Associate of Science degree in Nursing, in 1980, and a B.S. degree in Zoology/Physiology in 1987. Between 1980 and 1997 she was employed in the nursing profession. In 1996, she earned a M.S. degree at the University of Texas in Dallas, in Cognition and Neuroscience. In 1999, she completed a Ph.D. degree in Human Development and Communication Sciences / Cognition and Neuroscience. (Ex. 26, ECF. No. 46-3, p. 2.)

Dr. Kern served as a Research Fellow, then as a Senior Research Associate, in the Department of Psychiatry of the University of Texas Southwestern Medical School, from 1999 through 2002. She has been employed at the same Department of Psychiatry as an Assistant Professor, from 2002 to the present. Dr. Kern's *curriculum vitae* also describes her participation,

[17] Exhibit 17 was dated Nov. 11, 2007, but was not filed until June 6, 2013. (Ex. 17, ECF No. 36-2.)

as a researcher or consultant, in several organizations involved with autism, between 2000 and the present. (Ex. 26, pp. 3-4.)

b. Summary of Dr. Kern's opinion

The Petitioners filed two reports of Dr. Kern.[18] Both of Dr. Kern's reports provide a discussion of the *general* theory that thimerosal in vaccines can cause ASDs. (Exs. 25, 30.) Dr. Kern does *not* provide a case-specific opinion concerning the case of SRH. Essentially, Dr. Kern argues that the symptoms of autism are so similar to those of mercury toxicity that they are indistinguishable. (*Id*.) She theorizes that exposure to mercury causes neuronal injury, with microglial activation and neuroinflammation. (Ex. 30, pp. 23, 29.) She asserts that this process can result in "oxidative stress" and reduced glutathione levels in the brain. (*Id*., p. 36.) Also, she alleges that exposure to mercury "can result in mitochondrial dysfunction in the brain," which, she alleges, is also found in the brains of those with ASD. (*Id*. p. 40.) Dr. Kern alleges that mercury exposure causes a variety of chemical and molecular changes in brain cells that closely resemble the changes found in the brain cells of persons with ASD. (*Id*., summaries presented at pp. 40, 44, 51, 60, 61, 64, 67, 68.) Thus, she concludes, exposure to the mercury-containing thimerosal in vaccines "can cause or significantly contribute to the development of ASDs." (Ex. 30, p. 10.)

6. Petitioners' expert, Boyd Haley, Ph.D.

a. Qualifications

Dr. Boyd Haley received a B.S. degree in Chemistry/Physics from Franklin College in 1963. He completed an M.S. degree in Chemistry in 1967 at the University of Idaho, and his Ph.D. in Organic Chemistry in 1971, at Washington State University. He performed a postdoctoral fellowship at the Yale University Medical Center from 1971 through 1974. Between 1974 and 1985, Dr. Haley taught biochemistry, achieving the rank of full professor in 1981, at the University of Wyoming. From 1985 through 2007, he was a Professor of Medicinal Chemistry at the College of Pharmacy of the University of Kentucky, with concurrent appointments in Biochemistry and Chemistry. (Ex. 28, ECF No. 46-5, p. 1.)

As a scientific researcher, Dr. Haley has carried out numerous research grants for the National Institutes of Health and the Wallace Research Foundation. (Ex. 28, pp. 2-3.) His *curriculum vitae* lists more than 130 peer-reviewed articles that he has authored or co-authored, within his specialized area of expertise. (*Id*., pp. 10-18.) The primary focus of his research since 1987 has been the investigation of biochemical irregularities in Alzheimer's disease that he believes are indicative of mercury toxicity. (*Id*., p. 24.) More recently, he has investigated purported links between neurological problems and the use of mercury-containing dental

[18] Petitioners filed an expert report from Dr. Kern on Oct. 4, 2013. (Ex. 25, ECF 46-2.) On Oct. 8, 2013, a very similar report was filed as Ex. 30, ECF No. 49-2. Each report is 128 pages long, with discussion at pages 1-10, 15-68, and 112-21, while pages 11-14, 69-111, and 122-28 contain lists of references. (Exs. 25, 30.)

amalgams and vaccinations. (*Id*., p. 25.) Dr. Haley has given many lectures concerning these issues at medical schools, universities, and governmental forums. (*Id.*, pp. 4-8.)

b. Summary of Dr. Haley's opinion

Like Dr. Kern, Dr. Haley's report (Ex. 27, ECF 46-4) states only the *general theory* that thimerosal in vaccines can cause ASDs. He does *not* provide a case-specific opinion concerning SRH in particular. (*Id*.) Dr. Haley contends that the mercury contained in thimerosal, even in the tiny quantities contained in vaccines, can have adverse biological effects when administered to infants. (*Id*., p. 1.) He opines that "the cause of increased diagnosis of neurodevelopmental disorders in infants since 1990 is most likely due to the well-documented bolus exposure to thimerosal delivered through a vaccine in the first few months after birth." (*Id*., p. 8.) The younger the infant at the time of exposure, "the more significant the damage they are likely to incur." (*Id*.)

B. Respondent's experts

1. Respondent's expert, Bennett L. Leventhal, M.D.

a. Qualifications

Bennett L. Leventhal received a Bachelor of Science degree from Louisiana State University in 1972. (Ex. D, ECF No. 83-2, p. 1.) Dr. Leventhal graduated from Louisiana State University in 1974 with a degree in medicine. (*Id*.) He served as a resident in Psychiatry at Duke University Medical Center from 1974-1978. (*Id*., p. 2.) He also served as a Fellow in Child and Adolescent Psychiatry at the Duke University Medical Center. (*Id*.)

Dr. Leventhal is board-certified in both general psychiatry and child psychiatry. (Ex. D, p. 2.) He joined the faculty at the University of Chicago in 1978, rising from Assistant Professor of Psychiatry and Pediatrics, to Associate Professor, then full Professor. (*Id*., p. 3.) Also at the University of Chicago, he served for 25 years as Director of Child and Adolescent Psychiatry, and for eight years as Chief of the Department of Psychiatry. (Ex. C., ECF No. 83-1, p. 3 of 35.) From 2005 to 2009, he served as Professor and Director of the Center for Child Mental Health and Developmental Neuroscience at the University of Illinois. (*Id*.) From 2009 to 2014, Dr. Leventhal was the Deputy Director of Research and Vice Chairman of the Department of Child and Adolescent Psychiatry at the New York University School of Medicine. (*Id*.) In 2014, he joined the faculty of the University of California (San Francisco) as a Professor, and Director of Training in Child and Adolescent Psychiatry. (*Id*.)

Dr. Leventhal reviews medical literature submitted to numerous medical journals, and he is a member of the editorial boards of *Molecular Autism*, the *Journal of Autism Treatment and Research*, and the *Journal of Child and Adolescent Psychopharmacology*. He has 168 peer-reviewed publications listed on his *curriculum vitae*, along with 26 medical texts and book chapters, many of them pertaining to autism. (Ex. D. pp. 14-32, 45-47.)

b. Summary of Dr. Leventhal's opinion

Dr. Levental's report presented a comprehensive summary of the medical records filed in this case (Ex. C, pp. 4-28 of 35), including a highly detailed critique of the office notes recorded by Dr. Stephen Smith (*id.*, pp. 19-28). Based on his review of the records, he concluded that SRH's medical history "is consistent with an early onset neurodevelopmental disorder with significant delays and no substantial evidence of regression at any point in his development, and especially not in any temporal relationship to his vaccinations in May 1999." (*Id*., p. 31.) He added that SRH's neurodevelopmental disorder includes an autism spectrum disorder. (*Id*., p. 29.)

Dr. Leventhal harshly criticized the medical practices of Dr. Smith in this case, alleging that he failed to perform essential medical services for SRH, while at the same time exposing him to various risky treatments with no established utility. (Ex. C, p. 34.)

Concerning the causation of SRH's condition, Dr. Leventhal opined that that vaccinations had no role. (Ex. C, pp. 34-35.) He noted that "[t]here is no evidence that [SRH] had any adverse reactions to any of his vaccines." (*Id*., p. 34.) He added that there is "no substantial evidence of regression at any point in his development, and especially not in any temporal relationship to his vaccinations in May 1999." (*Id*., p. 31.) Thus, Dr. Leventhal concluded that SRH "had an early onset neurodevelopmental disorder, beginning during fetal development or the first year of life, and following a more-or-less typical course of the gradual appearance of symptoms of broad based developmental delays." (*Id*., p. 35.)

2. Respondent's expert, Edward W. Cetaruk, M.D.

a. Qualifications

Edward Cetaruk earned a Bachelor of Science degree in biochemistry at the University of Massachusetts at Amherst, in 1986. He received his medical degree at New York University School of Medicine, in 1991. From 1991 to 1994, he performed a residency in Emergency Medicine at the University of Massachusetts Medical Center. From 1994 to 1996, he completed concurrent fellowships in Emergency Medicine Research at the University of Colorado Health Sciences Center, and in Medical Toxicology at the Rocky Mountain Poison Center in Denver. (Ex. G, ECF No. 83-5, pp. 1-2.)

Since 1996, Dr. Cetaruk has been an Attending Faculty Member at the Rocky Mountain Poison and Drug Center. He has been an Assistant Clinical Professor of Medicine since the year 2000, in the Clinical Pharmacology and Toxicology Section of the University of Colorado Health Sciences Center. In addition, since 2002, Dr. Cetaruk has served in the Adjunct Faculty of the National Center for Biomedical Research and Training at Louisiana State University. He has also maintained a private medical practice since 1996 at Toxicology Associates, in Denver, which is devoted entirely to the diagnosis and treatment of human diseases associated with toxic agents. (Ex. G, pp. 1-3; Ex. F, p. 2.)

Over the course of his career, Dr. Cetaruk has received board certifications from the American College of Toxicology; the American Board of Emergency Medicine (with special

qualifications in Medical Toxicology); and the National Board of Medical Examiners. His *curriculum vitae* lists numerous medical articles and book chapters that he has authored or co-authored. He has been invited to present lectures at dozens of medical conferences and medical schools in the United States, and internationally. (Ex. G, pp. 1-11.)

b. Summary of Dr. Cetaruk's opinion

Dr. Cetaruk's expert report presented evaluations of the vaccine-causation theories provided by Petitioners' experts. (Ex. F, pp. 1-2.) He concluded that Petitioners' experts provide "neither reliable scientific data (*i.e.*, cited references) nor a scientifically sound causation analysis in this case." (*Id*., p. 16.) He opined that mercury poisoning does not occur at the doses of mercury contained in vaccinations, and that the symptoms of actual mercury poisoning, in any event, would not manifest as autism. (*Id*.) Dr. Cetaruk argued that published peer-reviewed literature does not support the theory that vaccinations can cause or exacerbate an alleged regressive encephalopathy, in particular, or autism, in general. (*Id*., pp. 16-17.) He maintained that there is no reliable evidence of the existence of a sub-population of children "who are more vulnerable or susceptible to mercury toxicity from thimerosal-containing vaccines," due to mitochondrial disease or other factors. (*Id*.) In particular, he found no evidence that SRH's ability to detoxify or metabolize mercury was impaired. (*Id.* p. 17.) Dr. Cetaruk concluded that "thimerosal-containing vaccines are not implicated in the etiology of ASDs, in general, and did not cause and were not contributory to [SRH's] condition specifically." (*Id.*)

3. Respondent's expert, Gerald V. Raymond, M.D.

a. Qualifications

Gerald V. Raymond graduated from Fairfield University with a B.S. degree in Biology, in 1980. He received his medical degree from the University of Connecticut in 1984. He performed an Internship, then a Residency, both in Pediatrics, both at Johns Hopkins Hospital in Baltimore, from 1984 to 1986. Concurrently, he completed a fellowship in Pediatrics at Johns Hopkins University. (Ex. I, ECF No. 83-7, pp. 2-3.)

From 1986 to 1989, Dr. Raymond was a Resident in Neurology at Massachusetts General Hospital, while he completed a fellowship in Neurology at Harvard Medical School. He then completed a fellowship in Pediatrics at Harvard Medical School, from 1990 to 1993. In 1993, he was appointed Pediatric Neurologist at the Kennedy Krieger Institute in Baltimore, where he served continuously till the end of 2012. During the same time period, Dr. Raymond taught neurology at the Johns Hopkins School of Medicine. (Ex. I, pp. 2-3) He continues to teach neurology there as an adjunct professor, but his primary focus since 2012 has been at the University of Minnesota Medical Center, where he is the Director of Child Neurology, with a specialization in clinical genetics. (*Id*., p. 3; Ex. H, ECF No. 83-6, p. 3.) Dr. Raymond's current medical practice includes evaluating "children with autism and developmental delays for potential genetic etiologies." (Ex. H, p. 3.)

As a researcher, Dr. Raymond has authored or co-authored more than ninety-five peer-reviewed articles investigating pediatric and neurological issues. (Ex. I, pp. 3-9.) He reviews

medical articles for multiple medical journals. (*Id*., p. 15.) He has also contributed chapters to sixteen medical textbooks concerning pediatrics and neurology. (*Id*. p. 12.) Dr. Raymond has received board certifications in Pediatrics, Neurology, and Clinical Genetics. (*Id*., p. 14.)

b. Summary of Dr. Raymond's opinion

Based on a review of the medical records, Dr. Raymond summarized his view that SRH "is a boy with autistic features and intellectual disability with evidence of macrocephaly and overgrowth." (Ex. H, p. 8.) He noted that SRH's lab tests have revealed multiple genetic aberrations. (*Id*., pp. 3-4.) However, Dr. Raymond observed that numerous studies of the alleged associations between these particular genetic aberrations and autism have *not* indicated that they made any contribution to the causation of autism. (*Id*., p. 4.)

Dr. Raymond maintained that autism is the result of multiple causation factors (with many genetic influences), and it appears with a diversity of symptoms. (Ex. H, p. 3.) Just as the characteristics and severity of the condition may vary widely, he opined that there is no single identifiable cause that explains the many different presentations of autism. (*Id*.) Most importantly, Dr. Raymond cited numerous peer-reviewed studies that show no epidemiological association between thimerosal-containing vaccines and autism. (*Id*., p. 5.)

With regard to the specific symptoms manifested by SRH, Dr. Raymond observed that "[t]here was no acute encephalopathy or mention of any systemic reaction at any time around the administration" of SRH's vaccinations. (Ex. H, p. 4.) He states that, "it has not been demonstrated that [SRH] has a mitochondrial disorder." (*Id*., p. 7.) He concludes that in SRH's case, "there is no evidence of any causation or exacerbation by any of the immunizations received." (*Id*., p. 8.)

VI

SUMMARY OF MY DECISION

A. Procedural circumstances leading to this Decision without an evidentiary hearing

As demonstrated in the procedural history of this case in part III of this Decision above, the Petitioners have placed a mass of material into the record of this case, with some items of their evidence contradicting others. But throughout the case, their basic theory of causation has consistently been that the preservative contained in certain vaccines that SRH received, known as "thimerosal," which contains a small amount of mercury, has caused SRH to suffer from the severe neurodevelopmental disorder known as an "autism spectrum disorder," also described as "ASD" or "autism."

Thus, in their original Petition, their Amended Petition, and their Second Amended Petition, the Petitioners have alleged that "mercury poisoning" caused SRH's ASD, and that the first symptoms of the *initial onset* of that autism took place *after* SRH received a Hib vaccination, containing thimerosal, on May 26, 1999.

However, Respondent filed a motion to dismiss this case, pointing to significant evidence that the first symptoms of the *initial onset* of SRH's ASD took place *prior* to May 10, 1999. (ECF No. 82.) That would mean that Petitioners' sole claim in this case at that time, that the *initial onset* of SRH's ASD was vaccine-caused, would be barred under the Vaccine Act's statute of limitations, § 300aa-16(a)(2), because the petition in this case was not filed until May 10, 2002, three years after May 10, 1999. Therefore, apparently in light of Respondent's argument concerning the statute of limitations, Petitioners, rather than dismiss their case as untimely filed, chose instead to file a Second Amended Petition in which they added an *alternative* theory of causation. That is, in their Second Amended Petition, Petitioners added an alternative pleading that "[i]f the Special Master were to find that there were earlier symptoms of autism [that is, earlier than May 10, 1999], then the Petitioners allege that the vaccinations that [SRH] received within the three years prior to filing the Petition significantly aggravated his autism." (2nd Am. Pet, ¶ 18.)

In light of this change of theory apparently made in order to avoid dismissal of this case under the statute of limitations, in my Order filed on March 18, 2015, I instructed Petitioners to file "supplemental expert reports from any of petitioners' experts who will participate in the trial of this case, explaining why they support the theory stated in the [Second] Amended Petition." (ECF No. 92.) The above-cited language in my Order of March 18, 2015, contained an implicit warning that ***only*** those experts who filed supplemental reports supporting Petitioners' "significant aggravation" allegation in the Second Amended Petition would be welcome to testify at any evidentiary hearing, or considered in resolving the case. In response to my Order, however, Petitioners, in a Status Report filed on May 18, 2015, *declined* to file any supplemental expert reports in support of the alternative "significant aggravation" theory stated in their Second Amended Petition. (ECF No. 107.)

In these overall circumstances -- *i.e.*, (1) the Petitioners had specifically declined to file any supplemental expert reports supporting their new "significant aggravation" claim, and (2) their *existing* expert reports contained no substantial support for their new "significant aggravation" claim, I issued my Order of May 20, 2015, determining that the appropriate procedure to resolve this case would be to rule on the existing record, without an evidentiary hearing. (ECF No. 109.) Significantly, Petitioners *filed no response* to my Order of May 20, 2015. They *never requested*, in response to my Order, that I conduct an evidentiary hearing in this case, or explained why I should do so. (If they had actually requested an evidentiary hearing and supplied arguments as to why such a hearing should be held, of course, I would have considered such arguments.)

Further, under the applicable statute and Court rules, a special master has discretion whether or not to conduct an evidentiary hearing before deciding a case. (Under § 300aa-12(d)(2)(D) of the statute, the special master is encouraged to decide cases "without requiring routine use of oral presentations, cross examinations, or hearings." Under Rule 8(d) of the Vaccine Rules of this Court, a special master "may decide a case on the basis of written submissions without conducting an evidentiary hearing.") I exercised my discretion, concluding that an evidentiary hearing was not necessary in the overall circumstances of this case.[19]

[19] In numerous Program cases, special masters have elected to decide cases without an evidentiary hearing, and judges of this Court and/or the Federal Circuit have upheld such

In exercising my discretion to decide the case without an evidentiary hearing, I also considered several other factors. First, I considered that all of the Petitioners' pleadings and expert reports in this case depended on the theory that the "thimerosal" ingredient contained in certain vaccines can cause or aggravate autism. However, that very causation theory was litigated at *extreme length* in the second group of three OAP "test cases," as explained above. In those test cases, three different special masters, after listening to weeks of testimony from multiple ASD experts from around the world, and studying multiple medical studies from around the world concluding that there was no evidence of any correlation between thimerosal-containing vaccines and ASDs, each wrote very extensive opinions (310, 169, and 117 pages, single-spaced, in length). They found no persuasive evidence of a causal link between thimerosal-containing vaccines and autism, and found that the available evidence indicated strongly *to the contrary*. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

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exercises of discretion. *See, e.g., Burns v. HHS*, 3 F. 3d 415 (Fed. Cir. 1993) (not error for the special master to refuse to take testimony from petitioner's medical expert where the special master concluded that the expert based his opinion on facts not substantiated by the record); *Henderlong v. HHS*, No. 11-689V, 2013 WL 2254570 (Fed. Cl. Spec. Mstr. Campbell-Smith April 26, 2013) (special master denied compensation without a hearing when the petitioner's expert report was inadequate to support causation); *Reed v. HHS*, 69 Fed. Cl. 437 (2005) (judge found no error in dismissal of petition without evidentiary hearing); *Perrin v. HHS*, No. 99-562V, 2004 WL 2830169 (Fed. Cl. Spec. Mstr. Nov. 19, 2004) (special master denied compensation without an evidentiary hearing when petitioner's physician statements supporting causation were unexplained); *Christian v. HHS*, No. 03-1169V, 2004 WL 2059491 (Fed. Cl. Spec. Mstr. Aug. 31, 2004) (the special master rejected petitioner's claim without holding an evidentiary hearing); *Snead v. HHS*, No. 01-337V, 2002 WL 1906505 (Fed. Cl. Spec. Mstr. Jun. 28, 2002) (after reviewing written expert reports from both sides, the special master denied the claim without an evidentiary hearing.); *Hovey v. HHS*, 38 Fed. Cl. 397 (1997) (judge upheld the special master's denial of an evidentiary hearing and dismissal of the petition); *Duncan v. HHS*, No. 90-3809V, 1997 WL 75429 (Fed. Cl. Spec. Mstr. Feb. 6, 1997) (the special master determined, without an evidentiary hearing, that petitioner presented insufficient factual evidence and inadequate expert medical opinion in the form of written reports, to establish the petitioner's causation claim); *Bumanglag v. HHS*, No. 90-3673V, 1997 WL 53451 (Fed. Cl. Spec. Mstr. Jan. 22, 1997) (evidentiary hearing denied where petitioner was unable to present sufficient factual and medical evidence to justify a hearing); *Gurr v. HHS*, 37 Fed. Cl. 314 (1997) (judge found no error in the special master's decision to dismiss the case without conducting a hearing to hear the testimony of petitioner's expert witness); *Walker v. HHS*, 33 Fed. Cl. 97 (1995) (judge upheld determination of special master to deny compensation without hearing oral expert testimony); *Skinner v. HHS*, 30 Fed. Cl. 402 (1994) (judge upheld determination of special master to deny compensation without hearing oral expert testimony); *Boehmer v. HHS*, No. 90-317V, 1991 WL 242995 (Cl. Ct. Spec. Mstr. Oct. 31, 1991) (special master denied compensation without an evidentiary hearing); *Plummer v. HHS*, 24 Cl. Ct. 304 (1991) (judge sustained special master's denial of evidentiary hearing, noting that "[h]olding an unnecessary hearing wastes judicial time and money, and seriously prejudices other petitioners waiting their turn.")

Further, as also explained above, the three other OAP "test cases" alleging that ASDs could be caused or aggravated by vaccines were also rejected by three special masters in lengthy opinions, affirmed by three different judges of this Court, with two of those cases[20] affirmed again by two panels of the U.S. Court of Appeals for the Federal Circuit. *See 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).

And in the more than 20 individual Vaccine Act cases litigated since the test cases, alleging that various vaccines had caused or aggravated autism, multiple special masters of this Court have *uniformly* concluded that there was no substantial evidence of vaccine causation. See cases listed at section II, above.

Second, my knowledge of the experts who have filed expert reports for Petitioners provided strong indication that there would be no good reason to conduct an evidentiary hearing at which I could hear orally from those experts. Not only were those experts proposing a thimerosal causation theory that has been resoundingly rejected in prior Vaccine Act cases, as discussed above, there also are *particular* reasons why *each* of the Petitioners' experts seems to offer an unreliable opinion, especially in comparison to Respondent's experts. Those reasons will be discussed in detail below, in Section IX of this Decision.

Third, as will be demonstrated in detail in Section VIII of this Decision, below, all of Petitioners' experts who gave a case-specific opinion, as to SRH himself, based their causation opinions on a *clear misreading* of the facts of this case, as plainly demonstrated by the medical records of SRH. Many of the cases cited above at footnote 19 involved similar situations, in which a special master appropriately declined to grant an evidentiary hearing when the petitioner's experts based their opinions upon factual assumptions that were contradicted by the medical records.

Finally, this case must be considered within the context of the *overall* National Vaccine Injury Compensation Program. Filings under the Program have dramatically increased in recent years, so much so that in 2015 cases were being filed at *triple* the rate that they were filed in 2010. The special masters of this court, designated to decide these cases, now face nearly overwhelming numbers of cases on each of their dockets, being required to resolve many more cases than in past years, but with the *same number* of special masters. In these circumstances, in deciding whether to conduct an evidentiary hearing in any case pursuant to Vaccine Rule 8(d), a special master must consider the impact on his or her overall caseload, and decide which cases merit a full evidentiary hearing and which do not. In evaluating this case, I was mindful that two other special masters and I spent months from 2008 to 2010, intensely studying the question of whether the tiny amount of mercury contained in thimerosal-containing vaccines could plausibly cause or aggravate an ASD. The evidence was overwhelmingly to the contrary. And when I studied the Petitioners' expert reports filed in this case, combined with their refusal of Petitioners to file any supplemental expert reports to explain their sudden addition of a "significant

[20] The petitioners in the third case, *Snyder*, did not appeal the decision of the judge of this court to the Federal Circuit.

aggravation" theory, I concluded that with so many cases on my docket in which the petitioners' theory at least appears somewhat plausible on its face, there was no good reason to conduct an evidentiary hearing in this case.

B. Summary of reasons for denial of Petitioners' claims

First, as demonstrated in part VII(A) of this Decision, the Petitioners' *primary* entitlement theory, that the *initial causation* of SRH's ASD was caused by a series of thimerosal-containing vaccines, must be dismissed pursuant to the Vaccine Act statute of limitations. (See Section VII(A) of this Decision below). Second, *both* of the Petitioners' causation theories, that the *initial causation* of SRH's ASD was produced by thimerosal-containing vaccines, and their *alternative* theory that thimerosal-containing vaccinations received on May 26, 1999, caused a *significant aggravation* of SRH's ASD, are shown by the record of this case to be wholly without merit.

As to the latter point, there are several reasons to reject the Petitioners' theory that thimerosal-containing vaccines *either* can *initially cause* an ASD or can *significantly aggravate* an ASD. One reason is that all three of the Petitioners' experts who gave case-specific opinions that the ASD of *SRH* was initially caused *or* significantly aggravated by his thimerosal-containing vaccines based their opinions on *clearly mistaken assumptions* about the facts of SRH's own medical history. (See Section VIII of this Decision.) A second crucial reason, set forth in detail at Section IX of this Decision, is that the qualifications of Respondent's experts were *overwhelmingly superior* to the extremely weak qualifications and reputations of Petitioners' witnesses. A third is that a comparison of the expert reports filed in this case demonstrates that the reports of Respondent's experts were also *far more persuasive* than the reports of Petitioners' experts. (See Section X of this Decision.) And a fourth reason, unnecessary to the resolution of this case but still quite significant, is that in the three OAP "test cases" addressing this very issue, three different special masters, after an exhaustive study of the available evidence from around the world, unanimously concluded that there is no persuasive evidence at all of a causal link between thimerosal-containing vaccines and autism. (See Section XII.)

Accordingly, for all the reasons discussed at length below, it is clear that *both* of the Petitioners' causation theories in this case must be rejected.

VII

ISSUE OF TIMELY FILING

A. The first of Petitioners' two causation claims is barred under the statute of limitations.

1. Petitioners' claims, and the relevant statute of limitations

In their original Petition, and their Amended Petition filed on July 20, 2011, the Petitioners alleged that "mercury poisoning," caused by the mercury in thimerosal-containing vaccines, caused SRH's ASD, and that the first symptoms of the *initial onset* of that ASD took place *after* SRH received vaccinations on May 26, 1999.

However, Respondent filed a motion to dismiss this case, pointing to significant evidence that the first symptoms of the *initial onset* of SRH's ASD took place *prior to May 10, 1999*. (ECF No. 82.) That would mean that Petitioners' claim in this case, that the *initial onset* of SRH's ASD was vaccine-caused, would be *barred* under the Vaccine Act's statute of limitations, § 300aa-16(a)(2), because the petition in this case was not filed until May 10, 2002, three years after May 10, 1999. Therefore, apparently in light of Respondent's argument concerning the statute of limitations, the Petitioners, rather than dismiss their case as untimely filed, chose instead to file a Second Amended Petition in which they added an *alternative* theory of causation. That is, in their Second Amended Petition, Petitioners added an alternative pleading that "[i]f the Special Master were to find that there were earlier symptoms of autism [that is, earlier than May 10, 1999], then the Petitioners allege that the vaccinations that [SRH] received within the three years prior to filing the Petition *significantly aggravated* his autism." (2nd Am. Pet, ¶ 18, emphasis added.) They followed up that alternative pleading with a document filed on March 23, 2015, which stated that the vaccinations which allegedly caused the *significant aggravation* were "the vaccinations that he received on May 26, 1999." (ECF No. 95, p. 18.)

The relevant part of the Vaccine Act's statute of limitations provides as follows:

> [I]f a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury.

§ 300aa–16(a)(2). Pursuant to this provision, a petition for compensation for an injury that is allegedly *initially caused* by a vaccine or vaccines, must be filed within thirty-six months of "the date of the occurrence of the first symptom or manifestation of onset" *of the injury*. *Wilkerson v. HHS*, 593 F.3d 1343, 1344 (Fed. Cir. 2010). *See also Cloer v. HHS*, 654 F. 3d 1322, 1335 (Fed. Cir. 2011) (holding that the statute of limitations in the Vaccine Act begins to run on the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury for which compensation is sought). And any claim that a pre-existing injury was "significantly aggravated" by a vaccine must be filed within thirty-six months of the first symptom of the *significant aggravation* of that injury. Claims regarding the initial causation of an injury, thus, are different from claims concerning significant aggravation, and the two issues must be analyzed separately.

In this case, Petitioners have ultimately advanced claims concerning *both* the initial causation and the significant aggravation of SRH's ASD. Their Petition was filed on May 10, 2002. Thus, in order for their *initial causation* claim to have been timely filed, the first symptom or manifestation of *onset* of SRH's ASD must have occurred *on or after May 10, 1999*; that is, within the thirty-six months before the petition was filed. Likewise, in order to comply with the Vaccine Act's statute of limitations, the first symptom of any *significant aggravation* must have occurred on or after May 10, 1999.

2. Petitioners' "initial onset" claim was untimely filed.

There are several reasons to conclude that SRH was exhibiting the *initial onset* of a neurodevelopmental disorder, later diagnosed as an autism spectrum disorder, *prior* to May 10,

1999. First, SRH's pediatrician, Dr. Heller-Bair, carefully recorded SRH's developmental progress during most pediatric visits during his first 15 months of life, using the Denver II Developmental Screening Test. (Ex. 35, pp. 4, 5, 11, 13, 24.) This screening tool allows medical personnel to indicate a "pass" ("P") or "fail" ("F") for each infant milestone, on a chart divided into age groups. At four months of age, Dr. Heller-Bair noted "fail" for three developmental milestones that SRH had not achieved. (Ex. 35, p. 24.) At six months of age, there are notations indicating that SRH failed to achieve three milestones. (*Id*.) At nine months, he failed two milestones, as he was not using "mama/dada" and could not sit up alone. (*Id*.) At his twelve-month check-up, on February 25, 1999, he could only speak two words, and was not yet able to drink from a cup. (*Id*.)

Second, Respondent's expert witness Dr. Leventhal, with by far the best qualifications regarding the study of ASDs of any expert who filed reports for either party in this case, reviewed SRH's medical records in exhaustive detail, and presented the following opinion regarding the time of onset of SRH's ASD.

> There is little doubt that [SRH's] early onset neurodevelopmental disorder began as early as 4 months of age. *Certainly, early signs of developmental disruption were present by 4-8 months of age* (trouble with changes in routine, sleep problems, noise hypersensitivity, staring at lights) with increasing evidence culminating in virtual certainty not later than 15 months of age when he was below expected levels on developmental examinations.

(Ex. C, p. 31, emphasis added.)

Dr. Leventhal also pointed to a lengthy list of unusual features of SRH's medical history exhibited *prior* to May 10, 1999, indicating the onset of ASD symptoms prior to that date. (Ex. C, pp. 29-30 of 35, ¶¶ a through h.) Included in that list of symptoms were a number of features that are particularly indicative of autism. For example, at his check-up on October 17, 1998, it was noted that SRH had "noise sensitivity." (Ex. 35, p. 7.) Dr. Leventhal pointed to that record, and explained that noise sensitivity "is a symptom associated with ASD (Autism Spectrum Disorder)." (Ex. C, p. 6; see also further discussion of noise sensitivity in SRH as a symptom of ASD by Dr. Leventhal at Ex. C, p. 7.)

Also included in Dr. Leventhal's list of early symptoms of developmental disorders was another symptom particularly indicative of ASD -- "evidence of language delay and reports of social interaction problems" at age 12 months. (Ex. C, p. 30, para. g.) Language delay and social interaction problems, are *classic* symptoms of autism. *See, e.g.*, *Snyder v. HHS*, No. 01-162V, 2009 WL 332044, at *31 (Fed. Cl. Spec. Mstr. Feb. 12, 2009).

Third, several representations by the *Petitioners themselves* indicate that SRH was suffering from developmental problems, likely early symptoms of his ASD, well prior to May 10, 1999. For example, SRH's parents reported that at one year of age (about February 10, 1999), he seemed "delayed in interactive skills." (Ex. 2, p. 46.) On September 14, 1999, SRH's parents reported that they had been worried about developmental delays "for about 6 months," which would put the onset around March of

1999. (Ex. 6, p. 19.) And on occasions, SRH's parents identified the onset of SRH's developmental problems as occurring about the time of his *MMR* vaccination, which took place on February 25, 1999. (See Ex. 5, p. 30 (SRH lost eye contact "after his MMR shot"); Ex. 14, p. 38 ("delays, deterioration of verbal skills coincidental [with] MMR")).

Accordingly, in light of Dr. Heller-Bair's records, Dr. Leventhal's expert analysis of the medical records, and Petitioners' own statements quoted above, Petitioners' *initial causation* claim, which has been their primary theory throughout most of the course of this litigation, must be considered *untimely filed*, since I find that SRH manifested symptoms of his ASD *prior to May 10, 1999*.

It is also quite telling, concerning this statute of limitations point, that after the Respondent on January 22, 2015, filed Respondent's Motion to Dismiss this case because it was untimely filed, along with Dr. Leventhal's expert report containing the analysis cited above supporting that conclusion, Petitioners did *not* file any expert report disagreeing with Dr. Leventhal's analysis on that point. To the contrary, they *declined* to file *any* further expert reports, as explained above. Instead, Petitioners reacted to the Respondent's statute of limitations argument merely by adding their alternative "significant aggravation" claim, which ensured that they had at least one claim, no matter how dubious, that would survive a motion to dismiss on timely filing grounds.

(However, even though I have found Petitioners' initial causation claim to be *untimely filed*, I will also demonstrate below that this initial causation claim was *also without merit*, even if it had been timely filed, since Petitioners have not come close to showing that any of SRH's vaccinations played any role in *either* the initial onset *or* a significant aggravation of his ASD.)

B. Petitioners' "significant aggravation" claim was timely filed.

Obviously, *if* the Petitioners could show (which they have not) that SRH's vaccinations of May 26, 1999, aggravated his ASD, as Petitioners now alternatively contend, then the first symptoms of that aggravation must have occurred after May 26, 1999. Therefore, *if* Petitioners could demonstrate the validity of their significant aggravation claim, then that claim was timely filed. (However, I note that for all the reasons set forth below, the Petitioners have *failed* to demonstrate that their significant aggravation claim has any *merit*.)

VIII

PETITIONERS' EXPERTS RELIED ON INCORRECT FACTUAL ASSUMPTIONS

A. The contemporaneous records contradict the factual assumptions of Drs. Smith and Megson.

One major reason that both Petitioners' causation claims must be denied is that Petitioners' experts relied on assumptions of fact, concerning SRH's medical history, that are *contradicted* by the contemporaneous medical records.

Both of Petitioners' primary experts based their opinions specific to SRH's case on erroneous factual assumptions. Dr. Smith stated in his report that SRH experienced a "regression" within two weeks of his 15-month vaccinations on May 26, 1999. (Ex. 29, p. 1.) And Dr. Megson stated that SRH experienced "a prolonged fever," "chronic inflammation," and "regressive encephalopathy" after those same vaccinations of May 26, 1999. (Ex. 32, p. 12.) However, the medical records *contradict* both Dr. Smith's assumption of a "regression" within two weeks of May 26, 1999, and also Dr. Megson's statements that SRH experienced "prolonged fever," "chronic inflammation," and "regressive encephalopathy" soon after May 26, 1999.

In this regard, I note first that I have carefully reviewed the contemporaneous records created around that time period, and have found no medical notations at all created between May 26, 1999, and June 8, 1999. Apparently, during those two weeks, SRH did not exhibit any adverse symptoms that seemed significant enough to result in a trip to his health care providers -- which certainly makes it seem impossible that SRH was in fact suffering, during those two weeks, any of the symptoms upon which Dr. Smith and Dr. Megson rely.

Even more importantly, SRH did visit physicians on several occasions between June 8 and June 30, 1999, and *none* of those records indicate that in late May and early June SRH had undergone a "regression," "prolonged fever," "chronic inflammation," or regressive encephalopathy," as stated by Drs. Smith and Megson. Those records, in fact, indicate to the *contrary*.

On June 8, 1999, SRH's parents brought him to the office of Dr. Randall Fong, an otolaryngologist, for an evaluation before surgery to place ear tubes. (Ex. 7, p. 4.) Dr. Fong noted SRH's ongoing ear issues, and an extensive pre-operative discussion with his parents, during which "all questions were answered, and informed consent was obtained." (*Id*.) There were no parental concerns noted regarding the recent onset of any neurological problems.

Six days later, on June 14, 1999, the pediatrician, Dr. Heller-Bair, examined SRH because he had a fever. (Ex 35, ECF No. 62-3, p. 14.) She recorded that he presented with a --

> 1-day history of low-grade fever, irritability, decreased appetite, nasal congestion. Child has a history of recurrent ear infections. Is scheduled for tympanostomy tube placement by Dr. Fong in about 4 days' time. Mom is concerned that he may have an ongoing ear infection prior to the surgery. (*Id*.)

Dr. Heller-Bair diagnosed a viral upper respiratory infection, but declined to prescribe antibiotics, and reassured SRH's mother that he did not have an ear infection at that time. (*Id*.)

On June 16, 1999, Dr. Fong performed another pre-operative examination of SRH. (Ex. 7, filed Oct. 4, 2007, p. 5.) He concluded that SRH appeared to be recovering from a viral illness, but he planned to proceed with the insertion of ear tubes on June 18, 1999, if there was no recurrence of fever. (*Id*.) Dr. Fong's pre-operative assessment, once again, did not describe any symptoms suggestive of a "regression" or neurodevelopmental problems of any kind. SRH, in fact, had his ear tube surgery on June 18, as planned, and Dr. Fong performed another complete examination just before that procedure. (Ex. 10, filed Oct. 4, 2007, p. 107.) He characterized SRH as a "well-developed, well-nourished white male in no acute distress." (*Id.*)

After the surgery, on June 30, 1999, Dr. Fong re-examined his patient and conducted a hearing test. (Ex. 7, p. 6.) The physical exam was unremarkable, while SRH's conductive hearing loss was somewhat "improved." (*Id.*)

Then, notably, for ten weeks, between June 14 and August 30 of 1999, SRH's parents did *not* bring him for evaluation by his pediatrician. There were no reports to Dr. Heller-Bair of adverse neurodevelopmental symptoms during this time period, although it is now claimed that SRH suffered a "toxic encephalopathy" or a "regression" soon after May 26, 1999.

In short, there is nothing in any of these many medical records, created during June 1999, that would lend any support at all to Dr. Smith's retrospective conclusion that SRH suffered a "regression" within two weeks soon after the vaccinations of May 26, 1999. Certainly, these physicians, especially the treating pediatrician, would have commented on such a regression if symptoms had actually appeared during the time period just prior to these physician visits.

Moreover, these physician records of June 1999 also directly contradict the assumptions upon which *Dr. Megson* based her opinion. Note that Dr. Heller-Bair on June 14 noted only a "1-day history of low-grade fever." (Ex. 35, p. 14.) This report of a "one-day" low-grade fever contradicts several allegations of fact in Dr. Megson's report, including her statements that after the May 26 vaccinations SRH experienced a "prolonged fever" (Ex. 32, p. 12); a fever from "May 26, 1999 to June 14, 1999,*** for 2 weeks" (Ex. 32, p. 3); and a fever "for 18 days" plus "3 additional days" (Ex. 32, p. 11).

Further, while Dr. Megson stated that SRH also experienced "chronic inflammation" and "regressive encephalopathy" after the May 26 vaccinations, the lack of any physician visits between May 26 and June 8, and particularly the above-described records of June 8 through June 30, also contradict those assumptions of Dr. Megson.

B. Even Dr. Smith's own medical records contradict the factual assumptions upon which he based his expert report.

It appears that the first contact between SRH and Dr. Stephen Smith occurred about fourteen months after the vaccinations at issue, on August 1, 2000. (Ex. 5, filed Sept. 7, 2007, p. 30.) During that first visit, Dr. Smith took a history, but failed to record *any notation* of a regression in SRH that took place during the two weeks after the vaccinations of May 26, 1999. (*Id*.) To the contrary, Dr. Smith's note seems to indicate instead that SRH "lost eye contact," most likely a symptom of SRH's ASD, "after his MMR shot," which took place on February 25, 1999, not on May 26, 1999. (*Id*.)

C. Petitioners' only additional expert that provided an opinion specifically concerning SRH also relied on an inaccurate factual claim about SRH.

As noted above, not only Drs. Smith and Megson, but also one other expert report presented by Petitioners, offered a case-specific opinion that SRH's ASD was affected by vaccinations. That was the opinion of Dr. Mark Geier. However, Dr. Geier also based this conclusion of vaccine-causation on an inaccurate assumption about the medical history of SRH. Like Drs. Smith and Megson, Dr. Geier stated the understanding that SRH "regressed at 15 month with a lost [*sic*] of words" (Ex. 17, p. 2 of 11), an allegation that is *contradicted* by the medical records cited above.

D. The Petitioners' representations concerning symptoms not appearing in the contemporaneous medical records

To be sure, it appears that at various occasions long after June of 1999, the Petitioners have made representations to the effect that SRH did experience certain additional symptoms soon after his vaccinations of May 26, 1999, symptoms that do *not* appear in the contemporaneous medical records. For example, Petitioners filed an affidavit of SRH's father on May 18, 2015, stating that SRH ran a low-grade fever from May 26 to June 14, 1999. (Ex. 62, ECF 108-2, p. 2 of 6.)

Further, in their Petition, Amended Petition, and Second Amended Petition, Petitioners alleged that SRH's father noticed a change in SRH's behavior, including loss of language, and loss of eye contact "following the May 1999 vaccination." (*See* Petition, p. 2; Am. Pet., p. 2; 2nd Am. Pet., p. 2.) They also filed another affidavit of SRH's father on April 7, 2015, stating that SRH suffered a profound regression "after May, 1999." (Ex. 60, ECF No. 102-02, p. 9 of 13.) However, these allegations in the three Petitions and in Ex. 60 do not state *how soon* after May 26, 1999, SRH suffered a behavior change and/or regression. Moreover, one document filed in late 2000 asserts that SRH's alleged reaction to the vaccinations of May 26, 1999, did not begin until about *67 days after* these vaccinations. (Ex. 50.)

In any event, after studying the *contemporaneous* medical records described above, recorded in June of 1999, I cannot credit as accurate any allegations describing any significant symptoms as occurring soon after May 26, 1999, since no such symptoms were reported during the many June 1999 physician visits. I find as fact that SRH did *not* suffer a "regression," "prolonged fever," "chronic inflammation," or "regressive encephalopathy" shortly after his vaccinations of May 26, 1999.

E. Summary: Petitioners' claim must be denied because their case-specific experts all relied on incorrect assumptions of fact.

To summarize this Section VIII of this Decision, each of Petitioners three experts, who expressed an opinion that *SRH* suffered a vaccine-caused injury, based their opinion on *incorrect assumptions* of fact. These expert opinions thereby lose any evidentiary value to Petitioners' case. Therefore, for this reason alone, I could reject Petitioners' claim and end my discussion of this case at this point. However, in the interest of completeness, I will, in the pages below, discuss *additional* reasons to reject Petitioners' claim in this case.

IX

RESPONDENTS' EXPERTS ARE *FAR* MORE QUALIFIED THAN PETITIONERS' EXPERTS

Another significant 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. Respondent's experts, Bennet Leventhal, 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 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. Stephen Smith, M.D.

The *curriculum vitae* of one of Petitioners' two primary experts, Dr. Stephen Smith, has not been filed. Thus, the only filed information concerning Dr. Smith's educational background and qualifications consists of his own brief statements about his practice contained in his expert report, plus copies of disciplinary rulings against him by a state regulatory agency.[21] As noted in Section V(A)(1), those rulings indicate that Dr. Smith graduated from medical school in 1980, and received a license to practice medicine in June 1981. (Ex. J, p. 6, ¶¶ 1.1, 1.2.) He did not complete any medical residency (*id*.), and is not board-certified in any medical specialty (Ex. K, p. 2, ¶ 2.1). He "practices allopathic medicine as well as alternative medicine." (Ex. J, ¶ 1.2.)

Dr. Smith's expert report filed in this case states that "I specialize in integrative medicine and chronic diseases such as autism, fibromyalgia and autoimmune disorders. I've been working with autistic children and children with developmental delays for over 20 years." (Ex. 29, p. 1.) However, there is nothing in the record of this case suggesting that he possesses any *specialized education or training* as an expert concerning *ASDs*.

Further, the above-mentioned disciplinary actions against Dr. Smith are directly relevant to the issues presented in this case. Exhibit J describes the ruling of the Washington State Medical Quality Assurance Commission ("Commission") in 2007, concerning Dr. Smith's prescription of "multiple traditional and non-traditional medications" to a teenage patient that Dr. Smith diagnosed as suffering from "mercury toxicity." (Ex. J, pp. 6-7 of 12.) The Commission determined that Dr. Smith subjected the patient to risky treatment without proper justification. (*Id*., pp. 7-8.) The Commission determined that Dr. Smith's actions constituted unprofessional conduct, and required that he undergo remedial training. (*Id*., p. 9.)

Exhibit K describes a ruling in 2014, concerning Dr. Smith's treatment of a different teenager, who had been diagnosed with autism. (Ex. K, p. 2 of 10.) In that case, Dr. Smith diagnosed a "toxic encephalopathy" related to lead poisoning (*id*., p. 4), and used a procedure known as "chelation" to treat the alleged excess lead in the patient's system (*id*., pp. 2-3). The Commission identified multiple failures by Dr. Smith to meet the standard of care for this patient, including his diagnosis of "toxic encephalopathy or lead poisoning despite the fact that

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[21] Respondent filed copies of official documents which describe disciplinary actions taken by the Department of Health of the State of Washington, against Stephen L. Smith, M.D., in 2007 and 2014. (Ex. J, ECF No. 83-8; and Ex. K, ECF No. 83-9, both filed on January 22, 2015.)

there was no evidence to support this diagnosis." (*Id*., pp. 3-4.) As a result of these findings, the Commission imposed a fine and prohibited Dr. Smith from treating patients under the age of 18. (*Id*., pp. 5-6.) In fact, he was forbidden to treat *any* patient without first demonstrating that the patient was concurrently under the care of some other primary care physician. (*Id*., p. 6.) The Commission also prohibited Dr. Smith from "using provocative agents prior to testing patients for heavy metal toxicity *** in his practice." (*Id*., p. 5.) Dr. Smith was forbidden to use any such tests performed by someone else "as a basis for diagnosing or treating heavy metal toxicity." (*Id*.) The ruling also prescribed that Dr. Smith would be subject in the future to periodic inspections of his office and medical records to guarantee compliance. (*Id.*, p. 6.) In short, Dr. Smith's medical practice was drastically restricted.[22]

Thus, Dr. Smith's credibility in this case, for a diagnosis similar to those he made in the disciplinary cases, is severely reduced, especially in comparison to Respondent's experts. He is not a credible expert.

B. Dr. Mark Geier, M.D., Mr. David Geier, and Janet Kern, Ph.D.

These three individuals (Mark Geier, David Geier, Janet Kern) share family and/or professional relationships, so that it is convenient to discuss them in conjunction with one another. Mark Geier is the father of David Geier, and Janet Kern has collaborated with both of them in producing many research papers. Their expert opinions concerning the alleged hazards of thimerosal-containing vaccines are very similar. And it is important to review the qualifications of these three individuals not only in order to evaluate the credibility of their own expert opinions, but also because the second of Petitioners' two primary experts, Dr. Megson, relied heavily on Dr. Geier's diagnoses to inform her own expert opinion. (*See* Ex. 32, p. 9.)

1. Dr. Mark Geier

It is quite surprising, and disappointing, that reports of Dr. Mark Geier were even filed in this case. In the course of the second set of "test cases" in the Omnibus Autism Proceeding, which addressed the theory that thimerosal-containing vaccines can cause autism, counsel for the petitioners submitted a medical article written by Mark Geier, David Geier, and a third party, supporting the thimerosal-causation theory. In *King v. HHS*, No. 03-584V, 2010 WL 5470787, *5-17 (Fed. Cl. Spec. Mstr. Dec. 13, 2010),[23] however, I found that it would be unreasonable for the Vaccine Program to compensate

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[22] Respondent's expert Dr. Leventhal, who is highly qualified in the treatment of autism, also harshly criticized the medical practices of Dr. Smith *in SRH's case*, alleging that Dr. Smith failed to perform essential medical services for SRH, while at the same time exposing him to various risky treatments with no established utility. (Ex. C, p. 34.)

[23] That *King* opinion was remanded to me for additional consideration, but on remand I issued another opinion that reached the same conclusion, based on the same evidence, concerning Dr. Geier. *See King v. HHS*, No. 03-584V, 2011 WL 5926126 (Fed. Cl. Spec. Mstr. Sep. 22, 2011).

counsel for paying Dr. Geier and his co-authors for writing the article. In that ruling, I described in great detail a multitude of criticisms of Dr. Geier's past expert reports and court testimony, both by many special masters of this court and by judges of other courts. Those criticisms related both to conclusions that he lacked his honesty and candor, and to his willingness to testify in medical areas in which he was not qualified. (*Id*. at *10-15.) I concluded that, based in part on my own and other judges' and special masters' stated opinions concerning Dr. Geier's honesty and credibility, I would not compensate petitioners' counsel for any of the services of Dr. Geier with respect to the autism-causation article in question. (*Id*. at *18-19.)

Nonetheless, in spite of my above-cited opinion in *King*, Petitioners filed two different expert reports of Dr. Geier in this case. (Ex. 17, filed on June 6, 2013; and Ex. 23, filed on October 4, 2013.)

Even more surprisingly, these expert reports were filed by Petitioners after the Maryland State Board of Physicians suspended Dr. Geier's license to practice medicine on April 27, 2011, and then *revoked that license* on August 22, 2012.[24] And even more disappointingly, when Petitioners filed a *curriculum vitae* of Dr. Geier on October 4, 2013, the fact that his medical license had been suspended and then revoked was *not mentioned*. (Ex. 24.)

It is further noteworthy that the Maryland State Board of Physicians ("Board"), in fact, based its actions against Dr. Geier on a review of Dr. Geier's medical care for multiple patients afflicted with ASDs. Among the many reasons given by the Board for revoking Dr. Geier's medical license were: a) his failure to meet basic medical standards for evaluating patients and keeping adequate records (Ex. A, p. 2); b) his prescriptions of chelation therapy to patients who did not need chelation (*id.*, p. 3); c) his administration of medications not approved by the Food and Drug Administration, without obtaining adequate informed consent, and his failure to properly monitor the outcome of such treatments (*id*., p. 4); and d) his willful falsification of his professional credentials (*id*., p. 5). The Board concluded that Dr. Geier had displayed "an almost total disregard of basic medical and ethical standards" (*id*., p. 14), and, "[i]n plain words, Dr. Geier exploited these patients under the guise of providing competent medical treatment" (*id*., p. 15).

In addition to his history as an expert witness of dubious honesty and credibility, as well as his medical license revocation, it is also noteworthy that Dr. Geier's medical professional training is poorly suited to providing an opinion in this case about the causation of ASDs. Dr. Geier's original medical specialty training was in gynecology and obstetrics, and he has practiced largely in the field of genetics. (Ex. 24, pp. 1-3.) In this regard, the Maryland State Board of Physicians included in its report a comment that Dr. Geier is not a "trained clinician." (Ex. A, p. 11.) The Board added that he "completed only a one-year residency in obstetrics and gynecology, has no formal specialized training in the treatment of autism, and is not Board certified in any medical specialty." (*Id*., pp. 11-12.)

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[24] See Exs. A and B, filed by Respondent -- Ex. B, p. 46, and Ex. A, p. 15.

Further, while Dr. Geier has published many medical articles concerning ASDs, the Institute of Medicine has evaluated a number of these articles and concluded that they are riddled with problems, and essentially without any value whatsoever in terms of contributing to the study of the causation of ASDs. *See King v. HHS*, supra, 2010 WL 5470787, at *12-14; *see also* Institute of Medicine, *IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM (2004)*, filed in this case on compact disc on June 2, 2015, as Respondent's Exhibit BBB, pp. 69-76 of 213.[25]

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[25] The Institute of Medicine is the medical arm of the National Academy of Sciences. The National Academy of Sciences ("NAS") was created by Congress in 1863 to be an advisor to the federal government on scientific and technical matters (*see* An Act to Incorporate the National Academy of Sciences, ch. 111, 12 Stat. 806 (1863)), and the Institute of Medicine ("IOM") is an offshoot of the NAS established in 1970 to provide advice concerning medical issues. (RML 255, p. iv.) When it enacted the Vaccine Act in 1986, Congress specifically directed that the IOM conduct studies concerning potential causal relationships between vaccines and illnesses. (§ 300aa-1 note.) In the intervening years, the IOM has formed committees which have prepared numerous reports concerning issues of possible relationships between vaccinations and injuries.

In 2004, the IOM assembled a committee to study the issue of whether thimerosal-containing vaccines can cause autism. That committee found that the evidence "favors rejection of causal relationship" between thimerosal-containing vaccines and autism. As part of their study, the Committee reviewed certain articles authored by the Geiers, and as discussed above, rejected those articles as without value. It is appropriate that I assign considerable evidentiary weight to the 2004 IOM committee's evaluation of the Geier articles. As noted above, when it enacted the Vaccine Act in 1986, *Congress specifically directed* that the IOM conduct studies concerning potential causal relationships between vaccines and illnesses. That direction obviously implies that when such studies are performed by IOM committees, a special master should carefully consider those studies in deciding Vaccine Act cases. Moreover, I note that during the 20-year history of the Vaccine Act, special masters have consistently relied upon the reports of the Institute of Medicine, and reviewing judges have consistently indicated approval of such reliance. *E.g., Terran v. Secretary of HHS*, 41 Fed. Cl. 330, 337 (1998) (affirming special master's reliance on conclusions of IOM), *aff'd*, 195 F. 3d 1302 (Fed. Cir. 1999); *Ultimo v. Secretary of HHS*, 28 Fed. Cl. 148, 152 (1993) (proper for a special master to rely on IOM report); *Cucuras v. Secretary of HHS*, 26 Cl. Ct. 537, 540 (1992) (same); *Manville v. Secretary of HHS*, 63 Fed. Cl. 482, 491 (2004) (same); *Ryman v. Secretary of HHS*, 65 Fed. Cl. 35, 39 (2005) (same); *Capizzano v. Secretary of HHS*, No. 00-759V, 2004 WL 1399178, at *2, n. 6 (Fed. Cl. Spec. Mstr. June 8, 2004) ("Considering the IOM's statutory charge, the scope of its review, and the cross section of experts making up the committee, the special masters have consistently accorded great weight to the IOM's findings."), *rev'd on other grounds*, 440 F.3d 1317 (Fed. Cir. 2006); *Larive v. Secretary of HHS*, No. 99-429V, 2004 WL 1212142, at *11 (Fed. Cl. Spec. Mstr. May 12, 2004); *Falksen v. Secretary of HHS*, No. 01-317V, 2004 WL 785056, at *13 (Fed. Cl. Spec. Mstr. Mar. 30, 2004) ("[T]he Court gives great deference to the findings of the Institute of Medicine on the issue of cause and effect between vaccines and discrete injuries."); *Malloy v. Secretary of HHS*, No. 99-193V, 2003 WL 22424968, *15 (Fed. Cl. Spec. Mstr. Aug. 6, 2003); *Hill v. Secretary of HHS*, No. 96-783, 2001 WL 166639, at *3-4 n. 2 (Fed. Cl. Spec. Mstr. Jan. 29, 2001); *Castillo v. Secretary of HHS*, No. 95-652V, 1999 WL

2. Mr. David Geier

A review of the 157 medical articles authored by Dr. Mark Geier, as listed in his *curriculum vitae,* reveals that his son, David Geier, was the co-author on a majority of them. (Ex. 24, ECF 45-5, pp. 5-16.) These two individuals, father and son, have collaborated for many years in publishing studies about autism spectrum disorders. However, David Geier, according to his own *curriculum vitae,* lacks any sort of medical education or training. (*See generally* Ex. 22.) In fact, his most significant qualification is a Bachelor of Arts degree, with a major in biology. (*Id*., p.1.) Based on this education and training, he does not have the credentials to prepare an expert report of any value in this case.

In this regard, I note that in *Riggins v. HHS*, No. 99–382V, 2009 WL 3319818, at *6–7 (Fed. Cl. Spec. Mstr. June 15, 2009), *aff'd*, 406 Fed. Appx. 479 (Fed. Cir. 2011), Special Master Golkiewicz found that David Geier was "not qualified to serve as a consultant on the medical issues presented in the Vaccine Program." I reached the same conclusion in *King v. HHS*, 2010 WL 5470787, at *20. Despite the rulings in *Riggins* and *King*, a report by David Geier was filed in this case. (Ex. 21, ECF No. 45-2, filed Oct. 4, 2013.) But that report of David Geier is neither useful nor relevant, because he is not qualified as an expert concerning the matters he discusses.

3. Janet Kern, Ph.D.

More recently, a number of the Geiers' articles have been co-authored by Janet Kern, Ph.D. It appears that Janet Kern commenced her collaboration with the Geiers in 2009,[26] even though the Geiers' previous medical research had been severely criticized, as described above. She contributed her own expertise to that affiliation, based on her Ph.D. degree in Human Development and Communication Sciences/Cognition and Neuroscience. (Ex. 26, ECF No. 46-3, p. 2.) She states that she is "a neuroscientist and autism researcher" who has published 34 peer-reviewed scientific research articles related to autism spectrum disorders. (*Id.*) Dr. Kern lists these articles in her *curriculum vitae,* including the 28 autism-related articles co-authored by Janet Kern, David Geier, and Dr. Mark Geier, during 2009-2013. (Ex. 26, pp. 6-9; *see also* Ex. 24, pp. 13-16.) Thus, 28 of the 34 autism-related articles that she has produced were co-authored by the Geiers. Within this group of 28 articles, at least ten were published *after* her co-author, Dr. Geier, had his medical license suspended.[27] Dr. Kern's willingness to affiliate herself with Dr. Geier, who has been completely discredited, reflects very poorly on Dr. Kern's judgment and credibility. The 28 autism-related articles that Dr. Kern co-authored with the Geiers have, in my view, greatly reduced her credibility as an expert.

605690, at *11 (Fed. Cl. Spec. Mstr. July 19, 1999); *Schell v. Secretary of HHS*, No. 90-3243V, 1994 WL 71254, at *5 (Fed. Cl. Spec. Mstr. Feb. 22, 1994).

[26] Dr. Kern's *curriculum vitae* includes a list of her publications. (Ex. 26, ECF No. 46-3, filed Oct. 4, 2013, pp. 4-9.) Among the items listed, all the papers that Dr. Kern co-authored with the Geiers are dated between 2009 and 2013. (*Id*., pp. 6-9.)

[27] At least ten of the articles co-authored by Dr. Kern and Dr. Geier were published in 2012 or later; that is, after Dr. Geier had his license suspended on April 27, 2011. (*See* Ex. B, p. 48.)

In addition, Dr. Kern is not a medical doctor. She does not have any significant qualifications in toxicology or epidemiology, and Respondent's witness Dr. Raymond pointed out that Dr. Kern "has no background in developmental neuropathology." (Ex. H, p. 5.) Accordingly, her opinions have far less persuasive weight than those of Respondent's experts (Drs. Leventhal, Cetaruk and Raymond), who are all medical doctors with advanced training in specialties that are relevant to this proceeding.

In sum, the expert reports of Mark Geier, David Geier, and Janet Kern do not add any persuasive weight to Petitioners' arguments. There is no reason to think that their opinions are at all reliable. These opinions come from individuals of questionable honesty and/or qualifications, or whose qualifications pale in comparison to those of Respondent's experts in this case.

C. Boyd Haley, Ph.D.

As noted above, in Section V(A)(6)(a), Dr. Haley has substantial qualifications at several universities as a researcher and a professor of chemistry and biochemistry. (*See* Ex. 28, ECF No. 46-5.) Based on those credentials, his opinions regarding chemistry and biochemistry might deserve a certain amount of deference -- but only his opinions in those broad subjects. His qualifications regarding medical toxicology,[28] however, 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. (Ex. G, p. 1.) For the past 15 years, he has served as an Assistant Clinical Professor of Medicine at the University of Colorado Health Sciences Center in the Division of Clinical Pharmacology and Toxicology. (*Id*.) For the past 19 years, he has served as an Attending Faculty Member at the Rocky Mountain Poison and Drug Center Fellowship in Medical Toxicology. (*Id*.) In that capacity, he has often diagnosed and treated patients with mercury exposure and mercury poisoning. (Ex. F, p. 5.) When I compare Dr. Cetaruk's specialized training and experience regarding the *medical* effects of mercury *on humans*, I find that his opinion on that subject carries far more persuasive weight than that of Dr. Haley, who is not a medical doctor, and whose expertise is in the more general fields of chemistry and biochemistry.

D. Mary Megson, M.D.

The qualifications of Respondent's expert Dr. Leventhal, concerning autism spectrum disorders, are much superior to those of Dr. Megson in that subject matter area.

Dr. Megson is a board-certified pediatrician who served four years as a Clinical Professor of Pediatrics at the Medical College of Virginia, before launching her own pediatric practice. (Ex. 33, ECF No. 58-3.) In her practice, to her credit, she has also treated a great many children with ASDs. *Long v. HHS*, No. 08-792, 2015 WL 1011740, at *7 (Fed. Cl. Spec. Mstr. Feb. 9,

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[28] 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 (31st ed. 2007), p. 1968. *Medical* toxicology deals specifically with the cause, diagnosis, and treatment of *human* disease associated with exposure to any potentially toxic agent.

2015). However, Dr. Leventhal has far superior *academic credentials* and *specialized medical training* in the area of ASDs, which is considered a psychiatric diagnosis as well as a neurological diagnosis.

Dr. Leventhal is board-certified in psychiatry, and in child psychiatry. (Ex. D, p. 2.) At the University of Chicago, he served for 25 years as Director of Child and Adolescent Psychiatry. (Ex. C, p. 3 of 35.) Currently, he serves as a Professor at the University of California San Francisco, as well as the Deputy Director of both the Child/Adolescent Psychiatry department and the Autism and Neurodevelopmental Disorders Program. (*Id*.) Dr. Leventhal has carried out multiple research grants concerning autism for the National Institutes of Health, the Illinois Department of Human Services, and other organizations. (Ex. D, pp. 12-13.) He is a reviewer for many prominent medical journals, and a member of the editorial boards of *Molecular Autism*, the *Journal of Autism Treatment and Research*, the *Journal of Child and Adolescent Psychopharmacology*, and the *Journal of Child and Adolescent Psychopharmacology*. (*Id.*, p. 12.) Dr. Leventhal has 168 peer-reviewed publications listed on his *curriculum vitae*, many of them pertaining to autism. (Ex. D, pp. 14-32.)

Thus, in terms of specialized medical training and practice relevant to autism, Dr. Leventhal has qualifications much superior to those of Dr. Megson. Likewise, Respondent's expert, Dr. Raymond, possesses distinguished credentials and experience in pediatric neurology, the other medical specialty most specific to the area of ASDs, while Dr. Megson does not.

I also note that I have myself heard Dr. Megson testify at length, in another case in which she advocated that a vaccination aggravated a child's ASD, and I found her to be a "very unpersuasive" witness. *Long v. HHS*, 2015 WL 1011740 at *19-20. (That was also another factor in my determination not to conduct an evidentiary hearing in this case.)

E. Summary concerning qualifications of experts

In summary, for the reasons pointed out in detail above, as to all of the experts whose reports were submitted by Petitioners, there are severe problems with the experts' qualifications to offer opinions either that thimerosal *can* contribute to the causation of ASDs in general, or that thimerosal-containing vaccinations *did* contribute to causing or aggravating the ASD of SRH himself.

In contrast, Respondent presented three medical doctors with excellent qualifications relevant to this case. As previously noted, Dr. Leventhal is board-certified in psychiatry, and in child psychiatry. (Ex. D, p. 2.) At the University of Chicago, he served for 25 years as Director of Child and Adolescent Psychiatry. (Ex. C, p. 3.) Currently, he serves as a Professor at the University of California San Francisco, as well as the Deputy Director of both the Child/Adolescent Psychiatry department and the Autism and Neurodevelopmental Disorders Program. (*Id*.) Dr. Leventhal has carried out multiple research grants concerning autism for the National Institutes of Health, the Illinois Department of Human Services and other organizations. (Ex. D, pp. 12-13.) He is a reviewer for many prominent medical journals, and a member of the editorial boards of *Molecular Autism*, the *Journal of Autism Treatment and Research*, the *Journal of Child and Adolescent Psychopharmacology*, and the *Journal of Child and Adolescent Psychopharmacology*. (*Id.*, p. 12.) Dr. Leventhal has 168 peer-reviewed publications listed on his *curriculum vitae*, many of them pertaining to autism. (Ex. B, pp. 14-32.)

Dr. Raymond is board-certified in pediatric neurology -- autism is a neurological as well as a psychiatric diagnosis. (Ex. I, p. 14.) He is the Director of Child Neurology at the University of Minnesota Medical Center. (*Id*., p. 3; Ex. H, p. 3.) Dr. Raymond's current medical practice includes evaluating "children with autism and developmental delays for potential genetic etiologies." (Ex. H, p. 3.)

Finally, Dr. Cetaruk is a medical doctor who has specialized in the study of medical toxicology, and is board-certified in that field. (Ex. G, ECF No. 83-5, p. 1.) For the past 15 years, he has served as an Assistant Clinical Professor of Medicine at the University of Colorado Health Sciences Center in the Division of Clinical Pharmacology and Toxicology. (*Id*.) For the past 19 years, he has served as an Attending Faculty Member at the Rocky Mountain Poison and Drug Center Fellowship in Medical Toxicology. (*Id*.) In that capacity, he has often diagnosed and treated patients with mercury exposure and mercury poisoning. (Ex. F, p. 5.)

Collectively, the qualifications of Respondent's three experts, to opine concerning the issue of whether thimerosal can contribute to the causation of ASDs, and whether SRH's vaccinations contributed to causing or aggravating SRH's own ASD, are *vastly superior* to the qualifications of Petitioners' experts. That is another major reason why I must rule against Petitioners in this case.

X

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

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

As explained in the previous section IX 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 were also *much more persuasive* than those filed by Petitioners' experts. As I have already explained in Section VIII of this Decision above, only three of Petitioners' experts actually provided opinions specific to SRH's case, and all three relied upon *incorrect* assumptions concerning SRH's medical history. Those three reports were completely unpersuasive for that reason alone. I have also read the expert reports of Mark Geier, David Geier, Janet Kern, and Boyd Haley, arguing the *general theory* that thimerosal-containing vaccines can cause or aggravate ASDs. But I found those reports to be poorly explained and unpersuasive in general, especially in comparison to the logical, well-reasoned, well-explained reports of Respondent's three experts.

1. General problems with Petitioners' causation theories and expert reports

In general, the *common theme* of all of Petitioners' expert reports is that the mercury in thimerosal-containing vaccines can damage the brain of an infant, causing neurodevelopmental disorders including autism spectrum disorders.[29] However, the Petitioners' expert reports fall far

[29] It is important to note that when Petitioners' experts diagnose SRH with "mercury poisoning," they are in effect saying that the mercury in SRH's thimerosal-containing vaccines

short of making a persuasive case that the amount of mercury in any thimerosal-containing vaccine, or in the *entire series* of thimerosal-containing vaccines that an infant received in this country at the time of SRH's infancy (almost all childhood vaccines *today* contain no thimerosal), can have any such effect.

While the Petitioners' expert reports stated the *conclusion* that thimerosal-containing vaccines can cause or aggravate an ASD, those reports were quite deficient in explaining *why* that might be so. Meanwhile, the reports of Respondent's experts explained persuasively that there simply is no scientific evidence supporting the theory that the amount of mercury in thimerosal-containing vaccines can cause autism, aggravate autism, or affect the infant brain in any way. They also noted that numerous well-designed epidemiologic studies have been conducted, and have consistently found *no association* between thimerosal-containing vaccines and autism.

In addition, I note that Petitioners' entire approach to their causation claim has been disjointed and inconsistent. Their expert reports generally seem to contend that the *cumulative* amount of mercury contained in a *series* of thimerosal-containing vaccines can cause an ASD, but some of Petitioners' *pleadings* are inconsistent with that approach. That is, Petitioners' Amended Petition and Second Amended Petition both pointed only to two vaccinations given on February 25 and May 26, 1999 -- one of which, the MMR vaccination given on February 25, *does not even contain* any thimerosal or any form of mercury.

Further, the only three of Petitioners' experts that express an opinion *specifically* concerning *SRH* are inconsistent with one another. For example, Dr. Megson, opined that SRH's earliest thimerosal-containing vaccines damaged his mitochondria, which allegedly made him more vulnerable to his later thimerosal-containing vaccines. (Ex. 32, pp. 10-11 of 12.) However, neither Dr. Smith (Ex. 29, pp. 1-2) nor Dr. Geier (Exs. 17, pp. 11 of 11) allege any mitochondrial damage to SRH.

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

2. No expert testimony supported Petitioners' "significant aggravation theory."

I also note that none of the Petitioners' expert reports provided any substantial support to Petitioners' alternative "significant aggravation" theory, their only theory that is not barred by the statute of limitations. Of the three reports that provide opinions specifically concerning SRH, the reports of Dr. Smith and Dr. Geier do not even mention "aggravation." (Exs. 17, 23, and 29.)

Dr. Megson's report on the other hand, does provide one paragraph alleging that unspecified vaccinations administered on May 26, 1999, "significantly aggravated an underlying mitochondrial disorder" of SRH. (Ex. 32, p. 11 of 12.) However, this brief allegation does *not* provide substantial support to Petitioners' "significant aggravation" claim, for several reasons.

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caused his ASD. Further, when those experts diagnose SRH with a "toxic encephalopathy," it is clear, based on the rest of their reports, that they are alleging that SRH's brain was damaged ("encephalopathy") by the alleged "toxin" consisting of the *mercury* in thimerosal-containing vaccines.

First, Dr. Megson bases her "significant aggravation" allegation on the assumption that after the May 26 vaccinations, SRH ran a fever for either 14 or 21 days (Ex. 32, pp. 3, 11) -- and as I have already demonstrated, that clearly was a *misassumption* of fact. Second, while Dr. Megson alleged aggravation of a "mitochondrial disorder," she never offered any persuasive evidence that SRH even had a mitochondrial disorder. To the contrary, Respondent's expert Dr. Raymond examined the record, and concluded that it has "not been determined that [SRH] has any evidence of mitochondrial DNA damage," and that "there is no clinical information that [SRH] has a progressive disorder of mitochondrial function." (Ex. H, p. 7.)

Third, Dr. Megson did not offer any persuasive discussion of *why* the small amount of thimerosal contained in SRH's vaccinations of May 26, 1999, might turn an "underlying mitochondrial disorder" into a serious neurodevelopmental disorder later characterized as an ASD.

In short, the record of this case contains no persuasive evidence for the Petitioners' "significant aggravation" theory, explaining how SRH's vaccinations of May 26, 1999, could have significantly worsened a pre-existing ASD or "mitochondrial disorder" in SRH. Indeed, this gaping hole in Petitioners' proof *by itself* would justify rejection of Petitioners' "significant aggravation" theory, their only claim in this case that was timely filed.

3. There are many specific flaws in Petitioners' expert reports.

In addition, the Respondent's expert reports also persuasively pointed out numerous *specific flaws* in Petitioners' expert reports.

For example, Petitioners' expert, Boyd Haley, Ph.D., stated that he found that thimerosal could be harmful when received "in the first few months after birth." (Ex. 27, p. 8.) But in this case, Petitioners' "significant aggravation" argument points exclusively to vaccinations administered on May 26, 1999, when SRH in fact was more than 15 months of age. Further, I found that Respondent's expert medical toxicologist, Dr. Cetaruk, was highly persuasive in his detailed critique of Dr. Haley's theory. (*See* Ex. F, pp. 6-11.) He effectively refuted Dr. Haley's reliance on certain scientific articles. (Ex. F, pp. 6-10). In particular, Dr. Cetaruk explained that mercury is not harmful to humans in the small amounts found in vaccinations, and that when mercury is harmful (at much higher doses), the harm "does not manifest as autism." (*Id*., p. 16.) Dr. Cetaruk also pointed out that Dr. Haley's theory, and many of the publications cited to support this theory, have already been reviewed and rejected by the Institute of Medicine.[30] (*Id*., p. 10.)

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[30] *See* Institute of Medicine of the National Academies, ADVERSE EFFECTS OF VACCINES: EVIDENCE AND CAUSALITY (Kathleen Stratton *et al*. eds. 2012) (Ex. AAA); Institute of Medicine of the National Academies, IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM (2004) (Ex. BBB); Institute of Medicine of the National Academies, IMMUNIZATION SAFETY REVIEW: THIMEROSAL-CONTAINING VACCINES AND NEURODEVELOPMENTAL DISORDERS (Kathleen Stratton *et al*. eds. 2001) (Ex. CCC).

Dr. Leventhal, with superb qualifications in the specific area of ASDs , and after a careful 25-page summary of SRH's medical history (Ex. C, pp. 4-28 of 35), did *not* find that vaccinations played any role in causing or aggravating SRH's neurodevelopmental disorder (*id*., pp. 34-5). Dr. Leventhal also specifically disagreed with Petitioners' significant aggravation argument, stating that there was "no substantial evidence of regression at any point in [SRH's] development, and especially not in any temporal relationship to his vaccinations in May 1999." (*Id*., p. 31.) Dr. Leventhal stressed that "[t]here is no evidence that [SRH] had any adverse reactions to any of his vaccines." (*Id*., p. 34.) He also explained that according to the medical records, in contrast to the assumptions of Petitioners' experts of an abrupt regression after the vaccinations of May 1999, SRH's developmental course in fact followed "a more-or-less typical course of the *gradual* appearance of symptoms of broad based developmental delays." (*Id*., p. 35, emphasis added.)

Similarly, Dr. Raymond's report noted that "there is no evidence from preclinical or clinical studies that vaccine administration has resulted in mercury toxicity or autism." (Ex. H, p. 5.) He pointed to the epidemiologic studies, cited at the end of his report (references 25-33), which all found no association between thimerosal-containing vaccines and autism, and concluded that "[t]here is no association between thimerosal-containing vaccines and autism." (*Id*.) He noted that a committee of the Institute of Medicine has *rejected* a causal relationship between thimerosal-containing vaccines and autism. (*Id*.)

Dr. Raymond's report also examined and refuted the Petitioners' expert reports. (Ex. H, pp. 4-8.) For example, he noted that Dr. Megson's report proposed that SRH's thimerosal-containing vaccines caused and then exacerbated a "mitochondrial disorder" in SRH. (*Id*., p. 6.) But Dr. Raymond examined the record for support for that proposal of Dr. Megson, and concluded that it has "not been determined that [SRH] has any evidence of mitochondrial DNA damage," and that "there is no clinical information that [SRH] has a progressive disorder of mitochondrial function." (*Id*., p. 7.)

I found Dr. Raymond's rebuttals of Dr. Megson, Dr. Kern, and Petitioners' other experts to be persuasive. Dr. Raymond concluded that in the case of SRH, "there is no evidence of any causation or exacerbation by any of the immunizations received." (Ex. H, p. 8.)

Finally, Dr. Cetaruk provided a third expert report strongly rebutting Petitioners' claim that SRH's autism was caused or aggravated by his thimerosal-containing vaccines. (Ex. F.) Dr. Cetaruk's report on this point provides a different form of persuasive rebuttal of Petitioners' case, since Dr. Cetaruk is not a psychiatrist or neurologist, but is a medical doctor specializing in *medical toxicology*, meaning the science of how substances can have a harmful effect on *humans*.

In his expert report, Dr. Cetaruk presented evaluations of the vaccine-causation theories provided by Petitioners' experts. (Ex. F.) He asserted that Petitioners' experts provide "neither reliable scientific data (*i.e.*, cited references) nor a scientifically sound causation analysis in this case." (*Id*., p. 16.) For example, Dr. Cetaruk extensively reviewed the report of Petitioners' expert, Dr. Haley, which advocated the *general causation* theory that the thimerosal in vaccines can damage infant brains, thereby causing autism. (*Id*., pp. 6-11.) He pointed out substantial flaws in the articles upon which Dr. Haley relied, explaining that the laboratory studies described in those articles did not yield relevant information as to whether the actual amount of mercury

contained in thimerosal-containing vaccines could have a detrimental effect on *live human infants*. (*Id*.) Dr. Cetaruk pointed out that the studies on which Dr. Haley relied involved amounts of mercury far higher than infants would receive from childhood vaccines. (*Id*.) One study, for instance, involved mercury levels *60* times higher than infants would receive from thimerosal-containing vaccines. (*Id*., p. 6.)

Dr. Cetaruk also reviewed the reports of Dr. Megson and Dr. Kern. (Ex. F, pp. 11-15.) He looked at the studies cited by Dr. Megson, found them flawed, and concluded that Dr. Megson presented "no scientific studies that provide a reliable basis for her theory that thimerosal causes or exacerbates mitochondrial dysfunction and/or causes chronic inflammation and/or causes autism in humans, either in general or specifically in the case of [SRH]." (*Id*., p. 11.)

Dr. Cetaruk likewise reviewed the arguments and articles relied upon by Dr. Kern, and pointed out problems with the articles that she relied upon. (Ex. F, pp. 12-15.) He noted, for example, that Dr. Kern had relied upon a *preliminary* description published in 1999 of a study by Verstraeten, but failed to discuss the *final*, full publication of the study, by Verstraeten in 2003, which found that there was *no association* between receipt of thimerosal-containing vaccines ("TCVs") and autism or other neurodevelopmental outcomes. (*Id*., pp. 14-15.)

Dr. Cetaruk also noted that Petitioners' expert Dr. Smith was wrong in his medical records to rely upon tests of hair mercury levels in SRH. He opined that reliance on hair mercury levels was not an accepted practice in medical toxicology. (Ex. F, p. 5.)

Dr. Cetaruk stated that he has extensively reviewed the scientific literature relevant to the theory that thimerosal-containing vaccines can affect the development or the exacerbation of autism. (Ex. F, p. 5.) He concluded that there is no reliable scientific evidence to support such theory. (*Id*., p. 17.) He stated that mercury is not harmful in the doses found in vaccinations. (*Id*., p. 16.) He found that the thimerosal-containing vaccinations received by SRH did not cause his ASD, and were not contributory to it. (*Id*., p. 17.)

B. Summary of Section X

In short, after reviewing all of the expert reports in this case, along with the accompanying medical literature, I found that Respondent's expert reports were *far more persuasive* than the reports of Petitioners' experts.

XI

FILINGS OF DR. BRIAN HOOKER

Various documents prepared by Brian Hooker, one of the Petitioners, have been filed in this case.[31] These filings include the resume of Brian Hooker (*see* Ex. 20, ECF No. 44-8), who

[31] *See e.g.,* Ex. 19, ECF No. 44-2 through 7, a 345-page document filed on Oct. 4, 2013; Ex. 20, ECF No. 44-8, an 18-page *curriculum vitae* of Dr. Hooker filed on Oct. 4, 2013; Ex. 60, ECF No. 102-2, a 12-page document filed on April 7, 2015, with the title "Affidavit of Brian

holds a Ph.D. in Chemical Engineering from Washington State University. He has had a distinguished dual career as a chemical engineering researcher and as a professor of biology and chemistry at the university level. (*Id*.)

In my review of the documents authored by Dr. Hooker, I find that they conflate his role as a Petitioner in this case with the role assigned to Petitioners' counsel. That is, Dr. Hooker has drafted some documents that make legal arguments concerning this case. He is not a lawyer. His legal arguments are sometimes articulate, but after reading them, I do not find that they change my view of this case, as stated in the sections of this Decision above.

Dr. Hooker's documents also conflate his role as a Petitioner with the role performed by Petitioners' experts. Based on his background as a chemical engineer and a professor of biology and chemistry, Dr. Hooker has offered his own opinions regarding medical and scientific issues that are central to this case. However, he is not a medical doctor, and his credentials to opine on the vaccine-causation issues in this case, are not comparable to those of Respondent's experts. I have read the opinions of Dr. Hooker regarding the causation issues in this case, but I find that they are not persuasive, and are far outweighed by the opinions of the Respondent's experts.[32]

Finally, I also note that Dr. Hooker alleges that vaccinations caused injuries to SRH other than his ASD. But I have studied the *expert reports* filed by Petitioners, and find that in essence they all argue either (1) the "general causation" argument that the mercury in thimerosal-containing vaccines *can* contribute to the causation of *ASDs*, or (2) that thimerosal-containing vaccines *did* initially cause or aggravate SRH's own autism spectrum disorder. After studying these Petitioners' expert reports, as well as the expert reports filed by Respondent and Dr. Hooker's filings, I conclude that Petitioners have *failed* to provide persuasive evidence that any of SRH's vaccinations, via the thimerosal preservative therein or by any other means, caused *any* damage to SRH.

XII

PETITIONERS RELY IN THIS CASE ON THE *SAME* CAUSATION THEORY THAT WAS *REJECTED* IN THE OAP "TEST CASES"

I reiterate that, for all the reasons set forth above, based *solely* upon the record of *this case*, I have concluded that the Petitioners have *failed* to demonstrate that it is "more probable than not" that any of SRH's vaccinations played *any* role in initially causing, or aggravating, his autism spectrum disorder.

However, it is also quite significant to reiterate that the *same* causation theory upon which the Petitioners rely in this case, the theory that the "thimerosal" preservative contained in

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Hooker in Response to Motion to Strike;" Ex. 62, ECF No. 108-2, a 5-page document filed on May 18, 2015, with the title "Affidavit of Brian Hooker."

[32] In addition, I note that Dr. Hooker's filings in this case allege improper actions by Respondent's attorneys. (*E.g.*, Ex. 60.) But I have reviewed the record and find no evidence of any improper conduct by Respondent's attorneys.

certain vaccines can cause or aggravate ASDs, was litigated at *extreme length* in the second group of three OAP "test cases," as explained above. Three different special masters, after listening to weeks of testimony from multiple ASD experts from around the world, and studying multiple medical studies from around the world concluding that there was no evidence of any correlation between thimerosal-containing vaccines and ASDs, each wrote very extensive opinions (310, 169, and 117 pages, respectively, single-spaced, in length), finding no persuasive evidence of a causal link between thimerosal-containing vaccines and autism, and finding that the available evidence indicated strongly *to the contrary*. *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Campbell-Smith Mar. 12, 2010); *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Vowell Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Hastings Mar. 12, 2010). Those three opinions detailed several major, very persuasive reasons to reject the theory that thimerosal-containing vaccinations can contribute to the causation or aggravation of autism. Some examples are noted below.

First, while different forms of mercury clearly can be quite harmful to humans at substantial doses (depending on the type of mercury), there is extensive scientific evidence showing clearly that the type of mercury contained in thimerosal-containing vaccines is *not* harmful to humans at the small amounts contained in thimerosal-containing vaccines. *E.g., King v. HHS*, 2010 WL 892296 at *29.

Second, extensive scientific evidence shows that when mercury *is* harmful to humans -- that is, when the human brain is exposed to dosages of mercury *far higher* than the amounts contained in all the thimerosal-containing vaccines that a young child would receive -- the harm looks *nothing like autism*. *E.g., King*, 2010 WL 892296 at *30.

Third, autopsy studies, comparing brains of autistic children to those of non-autistic children, indicate that autistic brains show a number of abnormal features that necessarily would have occurred during specific parts of the *prenatal period*, contradicting the theory that vaccinations received after birth could affect autism. *E.g., King*, 2010 WL 892296 at *32.

Fourth, in the first several years after the theory was first proposed that thimerosal-containing vaccines could cause ASDs, a large number of *epidemiological studies*[33] were carried out, in many countries world-wide, specifically to explore whether there was any association between exposure to thimerosal-containing vaccines and the occurrence of autism. *All* of the competent, well-designed studies reached the conclusion that *no association* between thimerosal-containing vaccines and autism had been shown. *E.g., King*, 2010 WL 892296 at *63-67, 75.

Fifth, a number of prestigious medical groups, including the Institute of Medicine; the World Health Organization; the American Academy of Pediatrics; the European Agency for the Evaluation of Medical Products; the U.S. Centers for Disease Control and Prevention; and the National Advisory Committee on Immunization of the Public Health Agency of Canada, have

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[33] Epidemiology is "the study of the factors determining and influencing the frequency and distribution of disease, injury, and other health-related events and their causes in a defined human population." *Dorland's Illustrated Medical Dictionary* (32nd ed. 2012), p. 631.

concluded that the scientific evidence does *not* support a causal relationship between thimerosal-containing vaccines and autism. *E.g., King*, 2010 WL 892296 at *75-77.

Thus, while, as noted above, the analysis of the evidence in *this case alone* thoroughly supports my ruling in this case, it is noteworthy that the extremely extensive and detailed analysis of those three "test-case" opinions, rejecting the *same theory* advanced by Petitioners here, also supports my conclusions in this case, as well as my determination to decide this case without holding an evidentiary opinion.[34]

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[34] As noted above, the record of *this case alone* clearly supports my rulings in this case. However, even if that were not the case, and it were necessary for me to rule in this case by utilizing the findings described above made in the autism "test cases," it would be appropriate to rely on that material in the course of deciding this case.

The chief reason is the very nature of the factfinding system set up under the Program. Congress assigned this factfinding task to a very small group of special masters, who would hear, without juries, a large number of cases involving a small number of vaccines. Congress gave these masters extremely broad discretion in deciding how to accept evidence and decide cases. (*See, e.g.*, § 300aa–12(d)(2).) Congress charged these masters to resolve such cases speedily and economically, with the minimum procedure necessary, and to avoid if possible the need for an evidentiary hearing in every case. *Id*.; *see also* H.R. Rept. No. 99-660, at 16-17 (*reprinted in* 1986 U.S.C.C.A.N. 6344, 6357-58). Congress even specified that a master should be "vigorous and diligent in *investigating*" Program factual issues (H.R. Rept. 99-660, *supra* at 17 (emphasis added)), in an "inquisitorial" fashion (H.R. Rept. No. 101-247, at 513 (*reprinted in* 1989 U.S.C.C.A.N. 1906, 2239)), indicating that a master can and should actively seek out, on his own, evidence beyond that presented by the parties to a particular case. Given this factfinding system, it would appear quite likely that Congress intended that the special masters would gain expertise in factual issues, including "actual causation" issues, that would repeatedly arise in Program cases. It would appear that Congress *intended* that knowledge and information gained by the masters in the course of Program cases would be applied by the masters to other Program cases, when appropriate. A number of published opinions have recognized that this Congressional intent is implicit in the factfinding system devised by Congress. *See, e.g., Lampe v. HHS*, 219 F. 3d 1357, 1362 (Fed. Cir. 2000) (acknowledging special masters' "accumulated expertise"); *Ultimo v. Secretary of HHS*, 28 Fed. Cl. 148, 152-53 (1993); *Loe v. Secretary of HHS*, 22 Cl. Ct. 430, 434 (1991).

It would also seem doubly appropriate for me to utilize findings from the OAP *autism* test cases in resolving this case, in which it is alleged that a child's *autism spectrum disorder* was vaccine-caused. The *very intent* of the Omnibus Autism Proceeding, set up at the behest of multiple Vaccine Act *petitioners*, was that an extensive inquiry into the "general causation" issues would be conducted, and then special masters would "apply the conclusions reached in that general inquiry to the individual cases." *Autism General Order No. 1*, 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002), at *2.

XIII

SUMMARY OF MY CONCLUSIONS CONCERNING PETITIONERS' CAUSATION CLAIMS IN THIS CASE

First, as demonstrated in part VII(A) of this Decision, the Petitioners' *primary* entitlement theory, that the *initial causation* of SRH's ASD was caused by a series of thimerosal-containing vaccines, must be dismissed pursuant to the Vaccine Act statute of limitations. (See Section VII(A) of this Decision above). Second, *both* of the Petitioners' causation theories, that the *initial causation* of SRH's ASD was produced by thimerosal-containing vaccines, and their *alternative* theory that thimerosal-containing vaccinations received on May 26, 1999, caused a *significant aggravation* of SRH's ASD, are shown by the record of this case to be wholly without merit.

As to the latter point, there are several reasons to reject the Petitioners' theory that thimerosal-containing vaccines *either* can *initially cause* an ASD or can *significantly aggravate* an ASD. One reason is that all three of the Petitioners' experts, who gave case-specific opinions that the ASD of SRH was initially caused *or* significantly aggravated by his thimerosal-containing vaccines, based their opinions on *clearly mistaken assumptions* about the facts of SRH's own medical history. (See Section VIII of this Decision.) A second crucial reason, set forth in detail at Section IX of this Decision, is that the qualifications of Respondent's experts were *overwhelmingly superior* to the extremely weak qualifications of Petitioners' witnesses. A third is that a comparison of the expert reports filed in this case demonstrates that the reports of Respondent's experts were also *far more persuasive* than the reports of Petitioners' experts. (See Section X of this Decision.) And a fourth reason, unnecessary to the resolution of this case but still of considerable significance, is that the three OAP "test cases" addressing this very same causation issue, three different special masters, after an exhaustive study of the available evidence from around the world, unanimously concluded that there is no persuasive evidence at all of a causal link between thimerosal-containing vaccines and autism. (See Section XII.)

Accordingly, for all the reasons discussed at length below, it is clear that *both* of the Petitioners' causation theories in this case must be rejected.

XIV

PETITIONERS' CASE FAILS THE TESTS REQUIRED BY *ALTHEN* AND *LOVING*

In the sections above, I have already made it clear in detail why Petitioners have *failed* to show, to the level of "more probable than not," that any vaccinations caused or aggravated the ASD of SRH. In an abundance of caution, however, in this Section of my Decision, I will explain how this case fits specifically within the interpretive standards set forth in the *Althen* and *Loving* decisions. The short answer is that I find that Petitioners' case clearly does *not* satisfy the standards presented in either *Althen* or *Loving*.

In this case, Petitioners contend (1) that thimerosal-containing vaccinations *initially caused* SRH's autism spectrum disorder, while alternatively arguing (2) that his vaccinations of

May 26, 1999, *significantly aggravated* a preexisting ASD. The distinction, however, does not matter to the outcome of this case, since it is clear that Petitioners rely on the same evidence to establish both claims, and have clearly failed to show *either*. In this Section of my Decision, I will, therefore, analyze Petitioners' case first under *Althen*, rejecting their "initial causation" argument. Then I will analyze Petitioners' case under the 6-part *Loving/Althen* test, rejecting their alternative "significant aggravation" claim.

A. Applying the Althen standard to Petitioners' "initial causation" claim

First, I will analyze the Petitioners' "initial causation" claim, utilizing the *Althen* standard.

The U.S. Court of Appeals for the Federal Circuit declared in *Althen* that it is a petitioner's burden:

> 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 vaccination and injury.

Althen, 418 F.3d at 1278 (citations omitted).

In this part of my Decision, then, I will briefly explain how my analysis in the *prior* sections of this Decision 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 "initial causation" claim in this case clearly does *not* satisfy the *Althen* test.

1. 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; [and] (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 vaccinee *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 SRH received contributed to the causation of his tragic autism spectrum disorder.

2. 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. Petitioners in this case have relied on the theory that the mercury in thimerosal-containing vaccines *initially caused* SRH's autism spectrum disorder. However, as discussed in Sections IX through XII above, Petitioners have *not* come close to demonstrating that these types of vaccinations *can* cause an autism spectrum disorder. As explained, the reports of Petitioners' experts simply contained no significant scientific evidence that thimerosal-containing vaccines can cause ASDs. Further, the qualifications of the Respondent's experts were far superior, and the explanations of Respondent's experts were far more persuasive. Thus, Petitioners' claim clearly fails under *Althen* Prong 1.

3. 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 SRH's vaccinations *did* initially cause SRH's *own* condition. But this they have also failed to do. Having failed to demonstrate Prong 1, Petitioner logically cannot have shown Prong 2, for the same reasons. Further, as demonstrated in Section VIII of this Decision, their claim must fail Prong 2 because all of Petitioners' experts who gave case-specific opinions concerning SRH relied upon *incorrect factual assumptions* about SRH's medical history.[35]

[35] In addition, Petitioners' "initial causation" claim with respect to SRH was *untimely filed*, as set forth in Section VII(A) above.

4. 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 further note that, as discussed at Section VII(A) and Section VIII above, the evidence indicates that the first symptoms of the *initial onset* of SRH's ASD occurred gradually at various times during SRH's first 15 months of life, not abruptly after any particular vaccinations. Therefore, Petitioners have failed to establish Prong 3 of *Althen* in this case.

B. Applying the Loving/Althen standard to Petitioners' alternative "significant aggravation" claim

Petitioners' alternative "significant aggravation" claim also must be rejected.

1. Analysis of a "significant aggravation" issue is guided by the ruling in Loving.

The Vaccine Act states that "[t]the term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain or illness accompanied by substantial deterioration of health." §300aa-33(4).

The elements of an off-Table significant aggravation case were set forth in *Loving v. HHS*, 86 Fed. Cl. 135, 144 (2009). The United States Court of Appeals for the Federal Circuit acknowledged that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims," in *W.C. v. HHS*, 704 F.3d 1352, 1357 (Fed. Cir. 2013). Thus, the Federal Circuit Court of Appeals, which sets binding precedent for decisions by the Office of Special Masters, endorsed the use of a six-part test for significant aggravation, which was first elaborated in *Loving*. A petitioner must prove by preponderant evidence that a vaccination caused significant aggravation by showing:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significant worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

W.C. v. HHS, 704 F.3d at 1357 (Fed. Cir. 2013).

The standard elaborated in *Loving*, and endorsed in *W.C. v. HHS*, combines elements from previous Federal Circuit decisions. *W.C. v. HHS*, 704 F.3d at 1537 ("The *Loving* test combines the first three *Whitecotton* factors, which establish significant aggravation, with the *Althen* factors, which establish causation.") Since the last three elements of the *Loving* test include the entirety of the *Althen* test, with insignificant

wording modifications, the analysis of those three elements would be the same using either standard.

2. Analysis of this case, under the six-part Loving/Althen test

In this Section, I will discuss why the Petitioners have failed to satisfy the six-part *Loving* test to establish the existence of vaccine-related *significant aggravation* of a preexisting condition.

a. What was SRH's condition prior to the administration of the vaccinations in question (i.e., for purposes of the "significant aggravation" claim, the vaccinations of May 26, 1999)?

The records show that prior to May 26, 1999, SRH generally *appeared* to be basically healthy. However, as detailed in Section VII(a) above, there is considerable evidence that SRH already had the initial symptoms of his ASD *prior* to May 26, 1999. Thus, on May 26, 1999, SRH generally *appeared* to be a healthy baby, but likely was already on his way to a significant ASD.

b. What was SRH's condition soon after the vaccinations in question, and what is his current condition?

As noted above (Section VIII), all of Petitioners' experts who gave a case-specific opinion about SRH -- Drs. Smith, Megson, and Geier -- based their causation theories in this case on the factual assertion that SRH suffered a "regression" and/or other specific symptoms soon after his vaccinations of May 26, 1999. However, for the reasons set forth in that Section, I have *rejected* those factual assumptions as mistaken. Therefore, I find that SRH's condition *soon after* the vaccinations in question was, contrary to Petitioners' factual allegations, *substantially unchanged* from his pre-vaccination condition.

However, on August 30, 1999, SRH's pediatrician expressed concern about his developmental delay and his decreased responsiveness to other people. Tragically, since then SRH has developed many other symptoms of a very significant neurodevelopmental disorder, which satisfies the criteria of an autism spectrum disorder. That is his "current condition."

c. SRH's current condition legally constitutes a "significant aggravation" of his prior condition.

As explained in the prior paragraph, I must *reject* Petitioners' allegation that SRH suffered a dramatic aggravation of his condition *soon after* the vaccinations of May 26, 1999. However, in the *Loving/Althen* formulation set forth in *W.C.* and quoted above, *one* question posed is whether the vaccinee's *current condition* constitutes a "significant aggravation" of the vaccinee's condition prior to vaccination. *W.C.*, 704 F.3d at 1357. As to *that* question, my conclusion is that SRH's "current condition" *is* "significantly worse" than his condition appeared immediately prior to the vaccinations in question. Therefore, following the legal standard set forth in *Loving* and *W.C.*, SRH's "current condition*" does* amount to a "significant aggravation" of his neurodevelopmental disorder (though the worsening has definitely *not* been shown to have been related to his *vaccinations*).

d. Petitioners have failed to establish Prong 4 of Loving/Prong 1 of Althen.

As discussed above, Prongs 4, 5 and 6 of the *Loving* test are, in effect, the same as Prongs 1, 2, and 3 of the *Althen* standard. Under Prong 4 of *Loving* and Prong 1 of *Althen*, a petitioner must provide a medical theory demonstrating that the *type* of vaccination in question can cause a significant worsening of the *type* of preexisting condition of the vaccinee. In this case, however, for the reasons stated above, in Sections IX through XII, the Petitioners have wholly *failed* to show that thimerosal-containing vaccinations *can* aggravate ASDs or any type of neurodevelopmental disorder. Therefore, Petitioners clearly have *failed* to establish Prong 4 of *Loving*/Prong 1 of *Althen* in this case.

e. Petitioners have failed to establish Prong 5 of Loving/Prong 2 of Althen in this case.

Under Prong 5 of *Loving*/Prong 2 of *Althen*, the Petitioners need to show that it is "more probable than not" that SRH's vaccinations of May 26, 1999, *did* aggravate the specific neurodevelopmental disorder of *SRH himself*. But they have failed to do so. As discussed in Section VIII above, all three of Petitioners' experts who opined that his vaccinations damaged SRH based their opinions on misassumptions of fact.

Accordingly, Petitioners have failed to establish Prong 5 of *Loving*/Prong 2 of *Althen* in this case.

f. Petitioners have failed to establish Prong 6 of Loving/Prong 3 of Althen in this case.

Since I have explained why Petitioners have failed to satisfy the *first* and *second* prongs of *Althen* (4th and 5th prongs of *Loving*), I need not discuss why Petitioners' case also fails to satisfy the Prong 3 of *Althen*/Prong 6 of *Loving*. However, I further note that, as discussed in Section VIII above, the evidence in this case *contradicts* the Petitioners' allegations that SRH manifested a "regression" and other symptoms, shortly after his vaccinations of May 26, 1999. Therefore, Petitioners have failed to establish Prong 6 of *Loving*/Prong 3 of *Althen* in this case.

g. Summary concerning Loving/Althen "significant aggravation" claim

Having failed to establish Prongs 4, 5, and 6 of *Loving*, Petitioners have failed to establish a "significant aggravation" claim in this case.

C. This 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." *Althen*, 418 F.3d at 1280. Accordingly, I note here that this case is *not* a close call. For all the reasons set forth above, I find that the causation theories of Petitioners' experts, both as to "initial causation" and "significant aggravation," were *not at all* persuasive, while the opinions presented by Respondent's experts were *far* more persuasive.

XV

CONCLUSION

The record of this case demonstrates plainly that SRH and his family have been through a tragic ordeal. I have also studied the records describing SRH's medical history, and the efforts of his family in caring for him. Based upon those experiences, the great dedication of SRH's family to his welfare is readily apparent to me.

Nor do I doubt that SRH's parents are sincere in their belief that SRH's vaccinations played a role in causing or aggravating SRH's autism. SRH's parents have heard the opinions of Dr. Smith, Dr. Megson, and other physicians who profess to believe in a causal connection between thimerosal-containing vaccines and autism. After studying the extensive evidence in this case, I am convinced that the opinions provided by Petitioners' experts in this case, advising the Hooker family that there is a causal connection between SRH's vaccinations and either the initial causation or aggravation of SRH's ASD, were *quite wrong*. Nevertheless, I can understand why SRH's parents found such opinions to be believable under the circumstances. I conclude that the Petitioners filed this petition in good faith.

Thus, I feel deep sympathy for the Hooker family. Further, I find it unfortunate that my ruling in this case means the Program will not be able to provide funds to assist this family, in caring for their child who suffers from a serious disorder. It is my view that our society does not provide enough assistance to families of *all* autistic children, regardless of the cause of their disorders. And it is certainly my hope that our society will find ways to ensure that in the future *much* more generous assistance is available to all such children. Such families must cope every day with tremendous challenges in caring for their autistic children, and all are deserving of sympathy and admiration. However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of individuals whose injuries or deaths can be linked causally, either by Table Injury or presumption or by preponderance of "causation-in-fact" evidence, to a listed vaccine. In this case, the evidence advanced by 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 SRH's behalf.[36]

IT IS SO ORDERED.

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

[36] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.