

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 03-234V

(Filed: May 1, 2009)

To be published¹

KATHALEEN STAPLEFORD, parent of Devon *
Stapleford, a minor, *

Petitioner, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

Vaccine Act Entitlement;
Causation-in-fact; Varicella
Vaccine/Seizure Disorder
Causation Issue.

*Ronald Homer and Sylvia Chin-Caplan, Boston, Massachusetts, for petitioners.
Linda Renzi, Department of Justice, Washington, D.C., for respondent*

DECISION

HASTINGS, *Special Master.*

This is an action in which the petitioner, Kathaleen Stapleford, seeks an award under the National Vaccine Injury Compensation Program (hereinafter “the Program”²), on account of an injury to her son, Devon Stapleford. For the reasons set forth below, I conclude that the petitioner is not entitled to such an award.

¹Because I have designated this document to be published, this document will be made available to the public unless a party files, within fourteen days, an objection to the disclosure of any material in this decision that would constitute “medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy.” See 42 U.S.C. § 300aa-12(d)(4)(B) (2006); Vaccine Rule 18(b).

²The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2006). Hereinafter, for ease of citation, all “§” references will be to 42 U.S.C. (2006). I will also sometimes refer to the Act of Congress that created the Program as the “Vaccine Act.”

I

THE APPLICABLE STATUTORY SCHEME AND CASE LAW

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 showings that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-lasting 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.³ 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)(A); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Secretary of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Secretary of 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 1278; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of 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 condition, but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Secretary of 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;" 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. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

³As will be detailed below, no Table Injury is alleged in this case.

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 a 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 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 the 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 factfinder 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. Secretary of HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program factfinders 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. Secretary of HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. Secretary of 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. Most recently, *DeBazan v. Secretary of 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.

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. Secretary of 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. One of the factors listed in *Daubert* is whether the scientific theory “has been subjected to peer review and publication.” 509 U.S. at 593. The Court noted that while publication does not “necessarily” correlate with reliability, since in some instances new theories will not yet have been published, nevertheless “submission to the scrutiny of the

scientific community is a component of ‘good science,’” so that the “fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity” of a theory. *Id.* at 593-94.

II

FACTS AND PROCEDURAL HISTORY

A. *Facts*

Devon Stapleford was born on December 22, 1999. (Ex. 1, p. 12.⁴) The medical records of his first year of life indicate that he appeared relatively healthy during that period. (*See generally* Ex. 4.)

On January 24, 2001, at his 13-month “well-child” visit, Devon received varicella (chicken-pox) and Prevnar (pneumonia) vaccines in the office of his pediatrician. (Ex. 4, p. 15.) At about 9:10 a.m. the next morning, Devon cried out, became limp, and trembled; when he had a second similar episode about 15 minutes later, his parents brought him to a hospital emergency room. (Ex. 6, pp. 73, 78.) By the time they reached the hospital, Devon had recovered enough to appear “playful and happy,” despite a fever of 100.5. (*Id.*) Nevertheless, the hospital physician concluded that Devon had suffered from seizures, diagnosing an “acute seizure disorder.” (*Id.* at 74, 78.) Devon was discharged in “good” condition. (*Id.* at 78.)

On January 27, 2001, Devon’s parents again took him to the emergency room, where it was recorded that he had suffered a “grand mal seizure” lasting one minute and 20 seconds. (Ex. 6, p. 69.) On January 30, 2001, a neurologist, Dr. Yacoub, examined Devon, and noted that, in addition to the identified seizures on January 25 and 27, Mrs. Stapleford had also observed episodes in which Devon blankly stared for 15-20 seconds at a time. (Ex. 4, pp. 141-43.) On the next day, January 31, 2001, Devon was admitted to a hospital again, with his mother reporting “on-going” seizure activity. (Ex. 6, p. 32.) Devon was placed on anti-seizure medication (“IV Dilantin”). (*Id.*)

On March 1, 2001, Devon visited another neurologist, Dr. Falchek. (Ex. 4, pp. 137-39.) Dr. Falchek noted that after Devon’s initial course of anti-seizure medication was discontinued in mid-February, he had experienced two additional seizures. (*Id.* at 137.) He also noted that other than the seizures, “Devon has been doing well developmentally. He had experienced no developmental regression * * *.” (*Id.*)

⁴Petitioner did not file any medical records with the petition. Petitioner filed Exhibits 1 through 15 on December 6, 2005, and additional exhibits on several occasions thereafter. Respondent filed Exhibit A on March 6, 2006, and additional exhibits on several occasions thereafter. “Ex.” references will be to those exhibits. “Tr.” references will be to the pages of the transcript of the evidentiary hearing held on December 18, 2006.

On April 24, 2001, Devon visited his pediatrician again. (Ex. 4, p. 14.) No further seizures were noted, although it was recorded that Devon did suffer a fever and rash for 48 hours. (*Id.*) On May 16, 2001, Devon was taken for a “multi-disciplinary evaluation,” on account of “concern for developmental delay due to a history of seizure activity.” (*Id.* at 126.) His development was found to be “age appropriate” in most areas, including the “cognitive,” “communication,” and “social/emotional” areas. (*Id.*) He was found to have a slight delay, of “less than 25%,” in the “adaptive” area. (*Id.*) During that evaluation, a physician noted that there had been a “recent increase” in Devon’s seizure episodes. (*Id.* at 128.)

On July 25, 2001, Devon received diphtheria-tetanus (“DT”) and hemophilus influenza (“hib”) vaccinations. (Ex. 4, p. 13.) On July 31, 2001, his mother called the pediatrician and reported that Devon had suffered additional seizures (“sz”) on the day after those vaccinations. (*Id.* at 8.)

On August 24, 2001, Devon’s mother reported to another physician that since Devon turned 18 months of age (in June of 2001) he had experienced seizures “approximately one time a week.” (Ex. 4, p. 110.)

On October 2, 2001, Devon again visited the neurologist Dr. Falchek, who wrote that Devon “is developmentally delayed,” “does not really speak,” and had experienced “behavioral disturbances.” (Ex. 4, pp. 108-09.) Dr. Falchek added that Devon “has an older brother with emerging autism, and his mother questions whether Devon is in fact following the same pattern.” (*Id.* at 108.) With regard to Devon’s seizures, Dr. Falchek noted that “his mother reports that they are occurring approximately every other day.” (*Id.*)

The medical records demonstrate that subsequently, Devon continued to suffer from a seizure disorder. For example, on October 8, 2002, it was recorded that Devon was undergoing three seizures per week (Ex. 4, p. 39), while on November 18, 2003, it was recorded that he was experiencing one or two seizures per month. (Ex. 5, p. 3.) In addition, his development continued to be poor. For instance, on November 15, 2002, Devon’s pediatrician wrote that Devon has “complex behavioral problems,” with “significant behavioral issues” that are similar to “autistic features.” (Ex. 4, p. 32.) On November 18, 2003, Dr. Falchek wrote that Devon had “Pervasive Developmental delay and Behavior Problems.” (Ex. 5, p. 4.)

The medical records, in general, further indicate that Devon has continued to suffer from seizures and severe developmental problems.

Devon’s medical records also include a number of references to Devon’s older brother, who apparently suffers from similar seizure and developmental problems. (Ex. 4, pp. 32, 68, 108, 138; Ex. 6, p. 62; Ex. 21, p. 2.)

B. Procedural history

The petition was filed on January 31, 2003. Proceedings were delayed for several years at the petitioner's request, as petitioner sought an expert opinion to support her claim. After petitioner filed an expert report, and respondent filed an expert report in response, I conducted an evidentiary hearing on December 18, 2006. At that hearing, the petitioner relied on the testimony of her expert witness Dr. David Griesemer, a pediatric neurologist. In response, respondent also relied on the expert testimony of a pediatric neurologist, Dr. Robert Snodgrass. At the hearing, petitioner's counsel requested that the parties file post-hearing briefs. The last of the post-hearing briefs was filed on May 21, 2007. Thereafter, however, additional post-hearing filings were made, as discussed in detail at pp. 27-30 below. At this time, the case is now ripe for a ruling concerning the issue of "entitlement," *i.e.*, whether the petitioner has demonstrated that she is entitled to a Program award on Devon's behalf.

III

ISSUE TO BE DECIDED

In this case, the petitioner seeks an award on Devon's behalf, contending that Devon's seizure disorder and his developmental problems were "caused-in-fact," at least in part, by his varicella vaccination received on January 24, 2001. After careful consideration, I conclude that petitioner has *failed* to demonstrate causation.⁵

IV

SUMMARY OF EXPERT OPINIONS

Concerning her allegation of causation-in-fact, petitioner relied primarily upon her expert witness, Dr. David Griesemer, a pediatric neurologist. Dr. Griesemer filed two expert reports prior to the evidentiary hearing, Exs. 14 and 17, and also testified at the evidentiary hearing in this case. Dr. Griesemer's opinion can be summarized as follows. He acknowledges that Devon probably had, from conception, a genetic defect which predisposed him to neurodevelopmental problems, and that even absent the varicella vaccination in question Devon likely would have had developmental delay, and possibly a seizure disorder as well. (*E.g.*, Tr. 20, 25, 27-28.) Dr. Griesemer believes, however, that the varicella vaccination likely changed the course of Devon's condition. He testified that the vaccine probably had a direct toxic effect upon the neurons of Devon's brain. (Tr. 16.) He also testified that the vaccination resulted in Devon having seizures earlier in his life than would

⁵Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." § 300aa-13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than not." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

otherwise have been the case, and that those early seizures themselves damaged Devon's brain, making his development worse than it otherwise would have been. (Exs. 14, 17; Tr. 11-35, 97-101.)

Respondent, on the other hand, relies primarily upon the opinion of Dr. Robert Snodgrass, also a pediatric neurologist. Dr. Snodgrass agrees with Dr. Griesemer that Devon, like his brother, had a genetic defect which destined him to suffer from seizures and developmental abnormality. Dr. Snodgrass, however, testified that he sees no good reason to conclude that Devon's varicella vaccination caused his seizure disorder and developmental problems to be any worse than they otherwise would have been. Dr. Snodgrass opined that there is no substantial evidence supporting the view that varicella vaccinations can cause seizures. He also testified that he sees no good reason to conclude that the type and frequency of seizures, from which Devon suffered during the period after the vaccination, would have caused any significant damage to his brain. (Ex. A; Tr. 40-46.)

After carefully considering the testimony of Dr. Griesemer, along with the testimony of Dr. Snodgrass and the other evidence in the record, I conclude that the evidence in the record does *not* support Dr. Griesemer's theory. The shortest explanation is that I simply found the reasoning of Dr. Snodgrass to be substantially more persuasive than that of Dr. Griesemer.

I note further, however, that Dr. Griesemer's analysis of Devon's case, in effect, breaks down into two parts. First, he opined that the varicella vaccine damaged the neurons of Devon's brain, thereby causing Devon to begin his seizures earlier than would otherwise have been the case. Second, he testified that those earlier seizures caused additional injury to Devon's brain, making his developmental outcome worse than it otherwise might have been. After consideration, I conclude that the evidence does not support a conclusion that *either* of the two parts of Dr. Griesemer's theory is "more probable than not." Accordingly, I will divide my principal discussions of those two parts of Dr. Griesemer's theory into the next two sections of this Decision, sections V and VI. I will then offer some additional general discussion in sections VII, VIII, IX, X, and XI.

V

DR. GRIESEMER'S THEORY, PART ONE

As noted above, the first part of Dr. Griesemer's causation theory is that the varicella vaccine caused Devon's seizures to begin earlier than would otherwise have been the case. Specifically, at the hearing Dr. Griesemer suggested that the varicella vaccine had "some direct toxic effect * * * on the neurons" of Devon's brain, thereby causing the onset of seizures. (Tr. 16.) However, after careful consideration I did not find this first part of Dr. Griesemer's causation theory to be persuasive.

A. *Primary analysis*

Dr. Griesemer's testimony concerning this point was extremely vague. He never *explained* his reasoning in that regard. He never explained *why* he believes that the varicella vaccine can harm

brain neurons. He never suggested a *mechanism* by which that vaccine could harm brain neurons. He admitted that “I do not have a specific understanding of the mechanism.”⁶ (Tr. 19.) He also admitted that he was “speculating” when he suggested that the varicella vaccine can directly attack brain neurons. (Tr. 33.) Thus, it appears to me, from an overall analysis of Dr. Griesemer’s reports and testimony, that he was, indeed, “speculating”--*i.e.*, merely theorizing, hypothesizing, guessing--in his assertion that the varicella vaccine caused the early onset of Devon’s seizures. I simply find his unexplained suggestion, about a possible toxic effect of the vaccine on brain neurons, to fall far short of constituting persuasive evidence that the varicella vaccine, more likely than not, harmed Devon’s brain.

Dr. Griesemer did testify that he knew of “reports” in the medical literature indicating that the varicella vaccine sometimes causes seizures. (Tr. 16, 24.) He stated that “the existence of seizures in response to varicella vaccine is established in the literature.” (Tr. 33.) In neither his prehearing expert reports nor his testimony, however, did Dr. Griesemer cite to any examples of such literature.⁷ Petitioner’s counsel, in cross-examining Dr. Snodgrass, did refer to an unnamed “article” concerning post-licensure safety monitoring of the varicella vaccine, which indicated that some recipients of that vaccine experienced seizures at various times thereafter. (Tr. 68.) After I asked petitioner’s counsel about the article, counsel volunteered to file the article after the hearing (Tr. 71), and petitioner subsequently did file that article as Ex. 22.

⁶It is true as a matter of law that the petitioner need *not* necessarily demonstrate the specific “mechanism” by which a vaccination may have injured a vaccinee, so long as there exists sufficient circumstantial evidence or other evidence to demonstrate that it is “more probable than not” that the vaccination caused the injury. *Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994). However, in the circumstances of this case, Dr. Griesemer’s inability to even suggest a *possible* mechanism adds to the general impression that his opinion here amounts to mere speculation. *See, e.g., Moberly v. Secretary of HHS*, 85 Fed. Cl. 571, 606 (2009) (dubious nature of the mechanism of injury proposed by petitioner’s expert may be considered as a factor militating against the credibility of that expert’s causation theory).

⁷In response to my own question, Dr. Griesemer stated that he had not cited to any such literature in his earlier written reports (*i.e.*, “the affidavit”), because he believed that “the role of varicella [vaccine] specifically causing seizures * * * was reasonably established in the literature.” (Tr. 35, lines 8-11.) However, when I later asked that the petitioner file the literature that supposedly “established” that the varicella vaccine *causes* seizures, petitioner was unable to do so. The only medical article eventually submitted by petitioners was the Wise article, Ex. 22, which, as will be discussed below, indicates only that a relatively small number of seizures have occurred after varicella vaccinations. That article certainly does not come remotely close to supporting Dr. Griesemer’s statement that it is “established” that the vaccine is “specifically *causing* seizures.” (Tr. 35, lines 8-11, emphasis added.) This indicates to me that Dr. Griesemer was willing to substantially exaggerate the nature of the medical literature.

A careful examination of Exhibit 22, however, reveals that it offers support to the opinion of *Dr. Snodgrass* rather than the opinion of *Dr. Griesemer*. The article⁸ reviewed reports of “adverse events” reported after varicella vaccinations during the first three years after that vaccination became licensed in the United States in 1995. It examined reports made under the Vaccine Adverse Event Reporting System (“VAERS”). According to the article, there were 163 reports of seizures (“convulsions”) occurring after varicella vaccination. (Ex. 22, p. 1276, and p. 1273 Table 2.) The data showed, however, that of those 163 reports of seizures, all but 54 occurred after the patient received both varicella vaccine and another vaccine at the same time. (*Id.* at 1273, Table 2, 4th column.) This factor makes it seem possible that it was *another* vaccination, received along with the varicella vaccination, that might have caused the seizures in those cases. Indeed, the article’s own authors pointed out that in many instances in which the vaccinee received the *MMR* vaccine along with the varicella vaccine and then a seizure occurred, the seizure took place during the *second week* after vaccination. (*Id.* at 1276.⁹) And, because it is well-recognized that the *MMR* vaccine sometimes does cause seizures in the second week after vaccination (as *Dr. Snodgrass* mentioned in his testimony in this case--see Tr. 41, 82), the authors then suggested that such timing makes them suspect that those second-week seizures were caused by the *MMR* vaccinations.¹⁰ The authors added that in only 25 of the cases did a seizure occur in a person who had received only the varicella vaccine and no other vaccine, and who also had no other evident reason to have a seizure (“had no evident pathology to account for convulsions”). (Ex. 22, p. 1276.) Further, in the article the authors made no suggestion, or even implication, that in even those 25 cases the seizures were *caused by* the varicella vaccinations.

At the hearing, *Dr. Snodgrass* testified that he had read that article, later filed as Ex. 22. (Tr. 68.) He discussed the article, explaining that he did not find the article helpful in judging whether the varicella vaccine actually caused any of the seizures described, because there is no way to tell whether the number of seizures in varicella-vaccinated individuals is higher than would occur *by chance* in non-vaccinated individuals. (Tr. 68-71, 81-82, 84-85.)

I found *Dr. Snodgrass* to be persuasive on this point. In 20 years of hearing Vaccine Act causation-in-fact claims, I have heard many expert witnesses explain that simply because Event B occasionally occurs *soon after* Vaccination A does not mean that Vaccination A *causes* Event B. Rather, causation can be reasonably attributed only if we have some type of evidence indicating that Vaccination A is *capable* of causing Event B--such as, for example, a study involving both

⁸ Robert P. Wise et al., *Postlicensure Safety Surveillance for Varicella Vaccine*, 284 JAMA 1271 (2000).

⁹The authors noted that “a larger proportion of reported seizures after administration of *MMR* with varicella vaccine occurred in the second week postvaccination than did reported seizures without preceding *MMR* * * *.” (*Id.* at 1276.)

¹⁰“Reported seizures after administration of varicella vaccine and *MMR* clustered in the second week * * *. These patterns support a role of *MMR* in post vaccination febrile seizures * * *.” (*Id.* at 1277.)

vaccinated and non-vaccinated individuals, which indicates that Event B occurs *more* frequently after Vaccination A than it occurs in non-vaccinated individuals.¹¹ Here, Ex. 22 indicates that there have been reports of 25 instances, over a three-year period, in which seizures occurred after an individual received varicella vaccination alone, and no other reason for the seizure was evident. However, during the time period in question, some *9.7 million* doses of varicella vaccine were sold (Ex. 22, p. 1271), so that it seems easily possible that the 25 instances occurred by chance alone. Accordingly, I found Dr. Snodgrass persuasive in his opinion that Ex. 22 does *not* provide persuasive evidence for the proposition that the varicella vaccine can cause seizures.

B. Analysis of post-hearing filings

As discussed in detail below (pp. 27-30), additional evidence relevant to this issue was filed into the record of this case after the evidentiary hearing. Several articles from the medical literature were filed, and each of the parties' experts filed two supplemental expert reports (Petitioner's Exs. 24 and 25; Respondent's Exs. E and I) discussing those articles. Taken together, those medical articles and expert reports support my conclusion that it has *not* been demonstrated that Devon's varicella vaccination caused his seizures on January 25, 2001, and/or caused the onset of his seizure disorder to occur earlier than it otherwise would have.

The most important of those articles was the Black article, which described a study that evaluated the safety and effectiveness of the varicella vaccine during a 21-month period after the vaccine became licensed for general use.¹² The study, involving more than 89,000 individuals who received the varicella vaccine, concluded that there was *no statistical association* between receipt of the varicella vaccine and seizures. (Ex. G, pp. 1041, 1044.) This study is important because it *specifically looked for* an association between the varicella vaccine and seizures, but found none. Thus, this study seems to provide significant support for Dr. Snodgrass' opinion that there is no good reason to conclude that the varicella vaccine can cause seizures.

¹¹This is not to say that causation can *never* be found to the level of "more probable than not," in a Vaccine Act case, in the absence of a supporting epidemiologic study. To the contrary, based on the circumstances of a particular case, causation *can* reasonably be attributed in the absence of an epidemiologic study, or in the absence of *any* supportive medical literature, based on circumstantial evidence or other evidence. *See, e.g., Althen v. Secretary of HHS*, 418 F.3d at 1274, 1279-80 (Fed. Cir. 2005). My point is simply that, as Dr. Snodgrass indicated, the fact that a certain type of event occasionally occurs after a certain type of vaccination does not necessarily constitute significant evidence that the vaccination *causes* the event. Such a determination, as to whether a *causal* connection has been shown, must be made by taking into account all the circumstances of the case.

¹²Steven Black et al., *Postmarketing Evaluation of the Safety and Effectiveness of Varicella Vaccine*, 18 PEDIATRIC INFECTIOUS DISEASE J. 1041 (1999). The study reached its conclusion, that there was no association between receipt of the varicella vaccine and seizures, *after* adjusting for the fact that some of the varicella vaccinees received the MMR vaccine, which is known to cause seizures, at the same time that they received the varicella. *Id.* at 1041, 1044.

Another article of significance was the Barlow article¹³ filed by respondent. Dr. Snodgrass, in one of his supplemental reports, explained that the article demonstrates that seizures, both febrile and nonfebrile, are relatively common in infants. (Ex. E, p. 1.) This means that the fact that seizures have been observed on rare occasions after varicella vaccinations, as reported in the Wise article, *cannot* reasonably be cited as evidence for a conclusion that the varicella vaccine can *cause* seizures. The fact that seizures are not uncommon in infancy, along with the fact that many millions of infants have received varicella vaccinations, means that it is hardly surprising that seizures have occasionally been observed shortly after varicella vaccinations. Such a coincidence would be expected to occasionally occur *by chance* alone.

Respondent also filed Exs. C and D, two articles that document clinical trials of the varicella vaccination before it was approved for general use.¹⁴ Both articles indicate that the vaccine trial results were examined for possible safety issues, and none were identified. (Ex. C, p. 521--“[n]o severe side effects;” Ex. D, pp. 114-115, 119--vaccine described as “sufficiently attenuated” and “safe.”) One would expect that if post-vaccination seizures had been observed in any appreciable number, that would have been reported, so that these articles perhaps add very slight support to Dr. Snodgrass’ view that there are no reasonable grounds for concluding that the varicella vaccine can cause seizures. However, neither article provided specific information as to whether *seizures* had occurred, so that these two articles are not of any significant evidentiary value concerning the seizure-causation issue here.¹⁵

C. Interpretation of Ex. 23, Physicians’ Desk Reference excerpt

1. Analysis of evidence concerning the Physicians’ Desk Reference in this case

Another exhibit that requires discussion is Ex. 23, an excerpt from the *Physicians’ Desk Reference* (“PDR”). The excerpt pertains to the “Varivax” vaccination, the brand name of the varicella vaccination that Devon received. In that excerpt, under the category of the “Adverse Reactions,” it is stated that, in children 1 to 13 years of age, “[f]ebrile seizures have occurred rarely

¹³William E. Barlow et al., *The Risk of Seizures After Receipt of Whole-Cell Pertussis or Measles, Mumps, and Rubella Vaccine*, 345 NEW ENG. J. MED. 656 (2001).

¹⁴Phillip R. Krause & Dennis M. Klinman, *Efficacy, Immunogenicity, Safety, and Use of Live Attenuated Chicken Pox Vaccine*, 127 J. PEDIATRICS 518 (1995) (Ex. C); F.E. Andre, *Worldwide Experience with the Oka-Strain Live Varicella Vaccine*, 61 POSTGRADUATE MED. J. 113 (1985) (Ex. D).

¹⁵The record also contains five exhibits that I myself placed into the record on February 5, 2008. Those are medical articles describing safety studies concerning varicella vaccinations. Each article seems to generally indicate that the varicella vaccine is safe, and/or that seizures have been observed only rarely after varicella vaccination. However, neither expert in this case, in their supplementary expert reports, placed any reliance on those exhibits. Accordingly, I have *not* placed any reliance on any of those exhibits in deciding this case.

(<0.1%) in children vaccinated with VARIVAX; a causal relationship has not been established.”¹⁶ It is also stated that in “adolescents and adults 13 years of age and older,” there have been reports of “non-febrile seizures” after varicella vaccination. (Ex. 23.) The filing of this excerpt from the PDR raises the question whether this excerpt supports Dr. Griesemer’s theory that the varicella vaccine can *cause* seizures. I conclude that the PDR excerpt does *not* offer substantial support to that theory.

After the petitioner filed Ex. 23, I asked both experts to address the issue of how to interpret that document. Dr. Snodgrass argued persuasively that the above-quoted statements from the PDR do *not* constitute significant evidence that the varicella vaccine can *cause* seizures. He explained that the content of the PDR, with respect to any particular vaccination, is mandated by regulations of the federal Food and Drug Administration (FDA). According to Dr. Snodgrass, when the PDR provides a list of possible “adverse reactions” to a vaccination, it is a list of events that have been *reported as occurring* after that vaccination, *without* a determination whether the events were actually *caused* by the vaccination. (Ex. I, p. 2.) Dr. Snodgrass so stated in his *part 3* of that report. (*Id.*) And Dr. Griesemer, in response, stated specifically that as to part 3 of Dr. Snodgrass’ report, “the comments of Dr. Snodgrass are factually correct, and I agree with them.” (Ex. 25, p. 2.)

Thus, Dr. Snodgrass and Dr. Griesemer have stated *agreement* that the fact that the PDR lists an event as a potential “adverse reaction,” reported to have occurred after a particular type of vaccination, *does not* mean that the vaccine manufacturer, the FDA, or anyone else has determined that the vaccine can actually *cause* that event. Moreover, Dr. Griesemer even added that “the PDR tends to present potentially inaccurate, imprecise, and incomplete data with regard to side effects” of vaccinations. (Ex. 25, p. 1.) Moreover, in none of his expert reports in this case has Dr. Griesemer ever stated that he finds Ex. 23 or the PDR to offer substantial support for his view that the varicella vaccine can cause seizures.

In addition, in the section of the PDR excerpted at Ex. 23, when the PDR notes that febrile seizures have “occurred rarely” (in less than one-tenth of one percent of vaccine recipients) in children receiving varicella vaccination, it specifically adds that “a causal relationship has not been established” between the vaccination and such seizures. (Ex. 23.)

Accordingly, based on the evidence filed in this case, I must conclude that the PDR’s listing of seizures, both febrile and nonfebrile, as events that have occurred after varicella vaccination, does *not* constitute substantial evidence that the varicella vaccination can *cause* any type of seizures. *Both* experts in this case have so indicated in their reports, and the wording of the PDR itself supports that conclusion.

¹⁶The excerpt filed by the petitioner is from the 2005 version of the PDR. (PHYSICIANS’ DESK REFERENCE 2166 (59th ed. 2005).)

2. Discussion of case law concerning PDR excerpts

Neither party to this case has cited or discussed any Vaccine Act case law concerning the use of the PDR in resolving causation issues. However, I have identified a number of opinions addressing that general topic. To be sure, rulings of judges or special masters of this court, concerning factual or legal issues, do not *bind* other judges or special masters in a legal sense. But such rulings can be of considerable *persuasive* value, so I find it appropriate to provide a discussion of the Vaccine Act opinions relevant to this issue of the PDR.

After studying those opinions, I conclude that the discussions in four of those opinions, in which special masters found PDR references *not* to be persuasive evidence that a vaccine can cause a particular type of adverse event, are of the most relevance and persuasive value concerning the causation issue in this case.

First, several opinions do not actually rely on the PDR in resolving specific causation claims, but merely offer a lengthy list of different types of “circumstantial evidence” that *might* be useful in resolving causation issues in Vaccine Act cases, and include “PDR citations” in that list. See *Pafford v. Secretary of HHS*, 64 Fed. Cl. 19, 29 (2005), *aff’d*, 451 F.3d 1352 (2006); *Stevens v. Secretary of HHS*, No. 99-594V, 2001 WL 387418, at *14 (Fed. Cl. Spec. Mstr. March 30, 2001); and a number of other opinions which simply quote the language in this regard from *Pafford*.¹⁷ Thus, those opinions offer no guidance as to what *particular* circumstances might justify using a statement from the PDR as evidence of causation.¹⁸

In four other Program opinions, it was noted that a *petitioner* had relied upon a PDR reference as part of the petitioner’s proffered causation proof, but the opinion did *not* further mention the PDR in its analysis of the causation issue. In three of those cases, the special master or judge found against causation, while in one case the special master ruled in favor of causation. *Cox v. Secretary of HHS*, 30 Fed. Cl. 136, 140 n.9 (1993) (no causation found); *Rindfleisch v. Secretary of HHS*, No. 03-1952V, 2005 WL 6117472, at *6 (Fed. Cl. Spec. Mstr. Dec. 13, 2005) (no causation); *Muchnick v. Secretary of HHS*, No. 90-703V, 1991 WL 217673, at *2 (Cl. Ct. Spec. Mstr. Oct. 10, 1991) (no causation); *Watson v. Secretary of HHS*, No. 96-639V, 2001 WL 1682537, at *5 (Fed. Cl. Spec. Mstr. Dec. 18, 2001) (causation found).

¹⁷*E.g.*, *Kelley v. Secretary of HHS*, 68 Fed. Cl. 84, 92 (2005); *Moreno v. Secretary of HHS*, 65 Fed. Cl. 13, 22 (2005); *Andreu v. Secretary of HHS*, No. 98-817V, 2008 WL 2517179, at *6 (Fed. Cl. Spec. Mstr. May 29, 2008).

¹⁸In a few other decisions, special masters have relied upon the PDR for a definition or a description of a vaccination, but not as an item of evidence to be used in resolving causation issues. See, *Doe 16 v. Secretary of HHS*, No. 06-670V, 2008 WL 2390064, at *2-3 (Fed. Cl. Spec. Mstr. June 2, 2008); *Doe 11 v. Secretary of HHS*, 2008 WL 649065, at *1 (Fed. Cl. Spec. Mstr. Jan. 31, 2008); *Durden v. Secretary of HHS*, No. 05-163V, 2007 WL 4962000, at *2 (Fed. Cl. Spec. Mstr. Sept. 26, 2007); *Finley v. Secretary of HHS*, No. 04-874V, 2004 WL 2059490, at *3 (Fed. Cl. Spec. Mstr. Aug. 24, 2004).

Next, in two other opinions special masters did indicate reliance upon PDR excerpts as *part* of their reasoning in concluding that a vaccination did play a role in causing an injury. In *Lee v. Secretary of HHS*, No. 03-2479V, 2005 WL 1125672, at *10, *12, *17 (Fed. Cl. Spec. Mstr. May 6, 2005), a special master concluded that a hepatitis B vaccination likely caused a severe headache in the vaccinee, citing PDR references indicating headaches to be a frequent side effect of that vaccine. In *Teller v. Secretary of HHS*, No. 06-804V, 2009 WL 255622, at *4 (Fed. Cl. Spec. Mstr. Jan. 13, 2009), a special master cited PDR pages as supportive of her conclusions that the DTaP vaccination can cause fever or “neurological reactions.”

However, it is clear that in the *Lee* case, the PDR reference played only a very limited role in the special master’s causation analysis. In *Lee*, the petitioner submitted, and the special master relied upon, several medical articles in addition to the PDR excerpt, as supporting the theory that the hepatitis B vaccination can cause headaches. 2005 WL 1125672, at *13. One of those articles, for example, described a study in which headaches were reported as a symptom in 9% of all vaccinees (*id.*); that evidence is a far cry from this case, in which the PDR stated that febrile seizures had occurred in *less* than 0.1% of vaccinees, and specifically added that “a causal relationship has not been established” (Ex. 23).

In *Teller*, on the other hand, the causation discussion was brief, so that it is not possible to precisely discern the importance of the PDR excerpt in the special master’s causation analysis, compared to other evidence in the record. However, the special master noted that according to the PDR, fever was a “relatively common” side effect of the vaccination in question. 2009 WL 255622, at *4. Again, that is far different from the situation here, where the PDR indicated that febrile seizures had occurred in less than 0.1% of vaccinees. (Ex. 23.)¹⁹

In four other opinions, however, special masters found PDR references *not* to be persuasive evidence that a vaccination had caused an adverse event. Upon careful study, those opinions seem to offer analysis that is more relevant and applicable to this case than the other opinions cited above.

In *Gilbert v. Secretary of HHS*, No. 04-455V, 2005 WL 3320085 (Fed. Cl. Spec. Mstr. Nov. 10, 2005), the petitioners contended that entries in the PDR establish that a vaccine can *cause* any adverse event listed in the PDR for that vaccine. Reviewing the nature and purpose of the PDR, however, Special Master Sweeney concluded that such a listing of an adverse event in the PDR does

¹⁹In two other opinions, special masters also seemed to possibly indicate reliance on the PDR as a part of their analysis in finding causation. In *Evans v. Secretary of HHS*, No. 90-3142V, 1997 WL 429719, at *12 n.8 (Fed. Cl. Spec. Mstr. July 15, 1997), a special master seemed to indicate reliance on the PDR for the proposition that a cough and other symptoms could be a reaction to the MMR vaccine. The opinion, however, did not provide a substantial discussion concerning the point. Similarly, in *Stevens v. Secretary of HHS*, No. 99-594V, 2006 WL 659525, at *12 (Fed. Cl. Spec. Mstr. Feb. 24, 2006), the special master noted that the PDR listed transverse myelitis as occurring in “greater than 1 percent after hepatitis B vaccination.” However, though the special master did find causation, she did not explain to what extent, if any, the PDR reference played a role in her causation analysis.

not constitute an admission or conclusion by the FDA that there is a causal association. 2005 WL 3320085, at *8.²⁰

The opinion in *Graves v. Secretary of HHS*, No. 02-1211V, 2008 WL 4763730 (Fed. Cl. Spec. Mstr. Oct. 14, 2008), though involving a different vaccine, involved a causation theory and a factual pattern quite similar to this case, and is, therefore, of considerable persuasive value concerning the causation issue in this case. In *Graves*, the petitioners contended that a pneumococcal vaccination caused their infant daughter's seizure disorder. For the contention that the pneumococcal vaccine can cause seizures, the petitioners' experts relied in part on an excerpt from the PDR. The special master found, however, that the PDR excerpt did *not* provide useful information as to whether that vaccination can cause seizures. 2008 WL 4763730, at *8.

In *Falksen v. Secretary of HHS*, No. 01-317V, 2004 WL 785056, at *13 (Fed. Cl. Spec. Mstr. Mar. 30, 2004), the special master noted that the petitioner relied on a PDR notation that "neurological complications * * * have been reported" after tetanus inoculations. The special master, however, concluded that this particular PDR notation "must be taken *cum grano saltis*"--*i.e.*, with a grain of salt--because "the PDR lists all possible reported complications without determining whether there is any causal link." *Id.* The special master denied the causation claim.

In *Fadelalla v. Secretary of HHS*, No. 97-573V, 1999 WL 270423, at *2 (Fed. Cl. Spec. Mstr. Apr. 15, 1999), the petitioner's expert, alleging that a case of Guillian-Barre Syndrome ("GBS") was caused by a rubella vaccination, relied upon a PDR excerpt. However, the special master, in denying the causation claim, noted that while the PDR stated that there had been "isolated reports" of GBS after rubella vaccination, the PDR further stated that "a cause and effect relationship has not been established." *Id.* at *2 n.2.

In sum, the Vaccine Act case law concerning the PDR indicates that in some instances (*Lee* and *Teller*, and possibly *Evans* and *Stevens*) special masters have relied at least in part on PDR excerpts while ruling in favor of causation. The *Gilbert*, *Graves*, *Falksen*, and *Fadelalla* rulings, however, provide persuasive examples of situations in which notations of an adverse event in the PDR do *not* constitute significant evidence that a vaccination can actually *cause* such an event. In my view, the important general lesson from those opinions is that the mere listing of a potential adverse event in the PDR section applicable to a particular vaccination should *not* automatically be viewed as evidence that the vaccination can *cause* that adverse event. As the evidence in this case demonstrates, adverse events may be listed in the PDR merely because they have been reported to occur after vaccination, without any determination by anyone as to whether it is plausible that the vaccination can actually *cause* such events. Rather, in any case in which a PDR excerpt is offered as evidence of causation, one must study the *particular* entry in the PDR. In some instances, the PDR may describe actual studies that *do* provide significant evidence pointing to a causal

²⁰The special master who decided *Gilbert* issued a similar ruling, utilizing identical language concerning the PDR issue, in a companion case. *Werderitsh v. Secretary of HHS*, No. 99-319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005).

relationship. But in other instances, the PDR may merely list an adverse event as having occurred, without providing any significant evidence as to causality.

In this particular case, I find that the particular PDR excerpt does *not* provide significant evidence concerning causation, for the reasons stated above.

D. Summary concerning Dr. Griesemer's part 1

Dr. Griesemer's theory that the varicella vaccine can cause seizures is essentially based on the facts that (1) it is proven that *some* types of vaccinations can cause seizures, and (2) some seizures have been reported after varicella vaccinations. In my view, that is not enough to establish that it is "more probable than not" that the varicella vaccine can cause seizures. As explained above, Dr. Snodgrass' testimony and the Barlow article establish that seizures in infants are not uncommon, so that it is clear that with *any* vaccination routinely administered to infants, there will be *some* reports of seizures occurring soon after vaccination. Therefore, under Dr. Griesemer's reasoning, it would follow that *any* seizure occurring soon after *any* type of infant vaccination would have to be deemed vaccine-caused, unless some other specific cause for the seizure was demonstrated. But this is a broader and more radical causation theory than has been adopted, to my knowledge, in any case in the 20-year history of the Vaccine Act. I simply do not find that Dr. Griesemer has offered sufficient evidence to support that approach.

That conclusion is reinforced by several other points noted above. Dr. Griesemer himself could not even suggest a possible *mechanism* by which the varicella vaccine might cause seizures. (See p. 8 above.) Dr. Griesemer also admitted that he was merely "speculating" in devising his theory. (See p. 8 above.) In addition, the Black study *specifically studied* the issue of a possible association between the varicella vaccine and seizures, but found no such association. (See p. 10 above.)

In short, for all of the reasons set forth above, I conclude that the evidence does *not* show that it is "more probable than not" that Devon's varicella vaccination caused his seizures on January 25, 2001, or caused the onset of his seizure disorder, or caused his seizure disorder to appear earlier than it otherwise would have.²¹

²¹Moreover, even if the petitioner had been able to demonstrate (which she did not) that the varicella vaccination of January 24, 2001, likely did trigger the *specific seizures* that occurred on January 25, 2001, Dr. Griesemer never explained how that occurrence might have caused Devon's *additional* seizures to appear earlier than they otherwise would have.

VI

DR. GRIESEMER'S THEORY, PART TWO

The evidence of record also does not support the *second* part of Dr. Griesemer's theory, that the occurrence of Devon's early seizures, earlier than otherwise would have been the case, caused additional injury to Devon's brain and thereby made his developmental outcome worse than it otherwise would have been.

On this point, once again Dr. Griesemer's testimony was exceedingly vague. He acknowledged that his opinion on this point was merely an "impression," adding that such impression is "something that I can't argue very convincingly." (Tr. 28.) He never suggested *when* he thinks Devon's seizures would have begun, absent the vaccination in question. Therefore, Dr. Griesemer never suggested how many weeks' or months' worth of earlier seizures Devon suffered, under his theory, as a result of the vaccination. Did Devon suffer a few extra weeks' worth of seizures, a few extra months' worth, or even more? Dr. Griesemer does not tell us. Accordingly, again Dr. Griesemer's theory seems very vague, and seems to amount essentially to speculation.

To be sure, petitioner did file three medical articles in an attempt to support this second part of Dr. Griesemer's theory. (Exs. 18-20.)²² Those three articles all do generally support the proposition that seizures in infants might in some instances have damaging effects on the developing brains. Dr. Snodgrass, however, explained that those articles rely primarily upon experiments in which researchers intentionally caused animal brains to undergo *very frequent, severe* seizures, thereby causing damage to the animal brains. (Tr. 46-47, 55-63, 75-77.) Dr. Snodgrass testified that those experiments involved seizures that were far more severe and/or far more frequent than the type of seizures that Devon suffered in 2001. (*Id.*) Dr. Snodgrass stated clearly and repeatedly the opinion that the type of seizures and the frequency of seizures that *Devon* experienced, during the period following his first seizure on January 25, 2001, were far *different* from the situations involved in Exhibits 18-20. (Tr. 45-46, 57-58, 75-77.) Dr. Snodgrass testified that he saw no reason to conclude that the seizures that Devon actually incurred during that time period would cause any significant damage to his brain. (Tr. 42-48, 57-58, 65-66, 75-77.) And, most crucially, after that clear testimony on that point by Dr. Snodgrass, petitioner offered *no rebuttal testimony* of Dr. Griesemer. To the contrary, Dr. Griesemer had previously acknowledged that the seizures from which Devon suffered were "not necessarily" the same type of seizures in the animal experiments that were the basis for Exhibits 18-20. (Tr. 24-25.) Thus, since Dr. Griesemer failed to even

²²Gregory L. Holmes & Yehezkiel Ben-Ari, *The Neurobiology and Consequences of Epilepsy in the Developing Brain*, 49 PEDIATRICS RES. 320 (2001) (Ex. 18); Frances E. Jensen, *Acute and Chronic Effects of Seizures in the Developing Brain: Experimental Models*, 40 EPILEPSIA S51 (1999) (Ex. 19); Carl E. Stafstrom, *Assessing the Behavioral and Cognitive Effects of Seizures on the Developing Brain*, 135 PROGRESS BRAIN RES. 377 (2002) (Ex. 20).

attempt to rebut this part of Dr. Snodgrass' presentation, I find that Dr. Griesemer failed to offer any persuasive evidence indicating that the type of seizures and the frequency of seizures, *that Devon actually suffered in 2001*, would likely have been sufficient to significantly damage his brain.

I find that the testimony of Dr. Snodgrass on this point was clear and persuasive. I find that the failure of Dr. Griesemer to offer any rebuttal on this point was devastating to the second part of Dr. Griesemer's theory. Further, after studying Exhibits 18 through 20 myself, I find those articles to be consistent with Dr. Snodgrass' descriptions of them. Accordingly, I conclude that the second part of Dr. Griesemer's theory, too, has *not* been shown to be "more probable than not."

VII

GENETIC DEFECT AS POTENTIAL CAUSE

As explained above, I do not find Dr. Griesemer's theory of causation to be "more probable than not." As explained, the record of this case does not demonstrate that *either* part of Dr. Griesemer's two-part theory is probable. Therefore, the petitioner did *not* made an adequate showing of "causation-in-fact" under 300aa-13(a)(1)(A). Accordingly, as a matter of law, the respondent in this case does *not* have any burden to demonstrate that Devon's seizure disorder and developmental delay were caused by some particular factor *other* than the vaccination. *See* § 300aa-13(a)(1)(B). Nevertheless, it is worthy of mention that the record in this case does offer considerable support to an alternative theory of causation of Devon's problems.

That is, *both* of the expert witnesses in this case, Drs. Griesemer and Snodgrass, agreed that Devon probably had, from conception, a *genetic defect* which predisposed him to neurodevelopmental problems. Dr. Griesemer acknowledged that even absent the vaccination in question Devon likely would not have been normal, would have had developmental delay, and quite possibly would have had a seizure disorder as well. (Tr. 20, 25, 27-28.) Dr. Snodgrass, too, testified that Devon had a genetic defect; in Dr. Snodgrass' view, such defect *completely explains* both Devon's seizure disorder and his developmental delay, which, in Dr. Snodgrass' view, would have been the same regardless of the varicella vaccination. (Ex. A, p. 3; Tr. 50-52.)

In addition, both experts indicated that Devon has a brother who, unfortunately, also has a seizure disorder and substantial developmental delay, probably also resulting from a genetic defect. (Tr. 48-49, 80-81; Ex. 4, pp. 32, 68, 108, 138; Ex. 6, p. 62; Ex. 14, p. 4, Ex. 21, p. 2.) The testimony indicates that the brother's seizure disorder began at a later stage in his life compared to Devon's history, yet their developmental outcomes appear to be similar. (Tr. 48-49, 80-81.)

Further, Dr. Snodgrass explained that a genetic defect can result in a seizure disorder and/or developmental delay *in the absence* of any environmental “trigger” to expose or bring out the defect. (Tr. 52, 54, 90-91.²³)

Thus, to be clear, it is unnecessary for me to determine that some other specific factor caused Devon’s seizure disorder and delay; I need only conclude that petitioner has *failed* to show that it is probable that the *varicella vaccination* caused or aggravated those conditions. However, I find that it is still instructive to note the following facts: (1) both experts agreed that Devon likely did have a genetic defect that predisposed him to neurodevelopmental abnormalities; (2) that Dr. Snodgrass explained that an environmental trigger is *not* necessary to bring out such a defect; and (3) that Devon’s brother had a genetic defect and ended up with very similar abnormalities, despite the fact that his seizure disorder started at a later point in his life. These facts, taken together, give me reason to credit Dr. Snodgrass’ theory that Devon’s genetic defect *completely explains* his seizure disorder and developmental delay. They, therefore, give me *additional* reason to doubt Dr. Griesemer’s speculative theory that the varicella vaccination caused or aggravated Devon’s seizure disorder.

VIII

ANALYSIS OF MEDICAL RECORD NOTATIONS CONCERNING CAUSATION

It is noteworthy that in the recent *Capizzano* opinion, the U.S. Court of Appeals for the Federal Circuit stressed that “medical records and medical opinion testimony are favored in vaccine cases, *as treating physicians are likely to be in the best position to determine* whether ‘a logical sequence of cause and effect shows that the vaccination was the reason for the injury.’” 440 F.3d 1317, 1326 (Fed. Cir. 2006) (emphasis added, citation omitted). Similarly, in several recent cases, judges of this court have, in resolving Vaccine Act causation issues, relied heavily upon the statements of treating physicians contained in the vaccinee’s medical records. *See, e.g., Zatushni v. Secretary of HHS*, 69 Fed. Cl. 612, 623 (2006); *Kelley v. Secretary of HHS*, 68 Fed. Cl. 84, 100 (2005).

Accordingly, in this case I have carefully reviewed the medical records of Devon’s treatment, in order to see whether those records shed any substantial light upon the issue of the cause of Devon’s seizure disorder and/or developmental delay, in the form of statements by his treating physicians. The short answer is that the medical records simply do *not* seem to provide any substantial evidence concerning the causation issue.

²³Dr. Griesemer did not make any attempt to refute this point of Dr. Snodgrass. Dr. Griesemer never testified that some sort of environmental trigger is necessary in order to expose or bring out a genetic defect.

A. Notations cited by petitioner

In this regard, petitioner points to 13 excerpts from Devon's medical records. (P. Brief filed 2-28-07, pp. 28-30). Petitioner argues that such excerpts "indicate that several medical providers associated Devon's varicella vaccine with his seizures." (*Id.* at 28.) A careful analysis of those excerpts, however, shows that those excerpts do *not* provide any substantial support to the proposition that the varicella vaccination *caused* Devon's seizure disorder and/or his developmental delay.

Eight of those excerpts merely amount to mentions in the medical records of the uncontested fact that Devon experienced his first seizures on the day after his vaccinations of January 24, 2001. In those eight excerpts, I simply perceive no suggestion or implication, by the person who wrote the statement, that the vaccination *caused* Devon's seizures the following day, or caused his ongoing seizure disorder thereafter. Those eight excerpts are as follows:

(1) Kent Memorial Hospital ER record of January 25, 2001 ("had seizure * * *. Had vaccinations (chicken pox and meningitis) 1/24/01"), Ex. 6, p. 78; (2) Kent Hospital ER, January 27, 2001 ("seen Thurs for seizures. Tonight had grand mal seizure, [which] lasted 1 minute 20 sec. Had chicken pox vac. on Wed."), Ex. 6, p. 69; (3) Neurologist Dr. Carl Yacoub, January 30, 2001 ("The patient * * * was seen for seizures that began after a varicella vaccination."), Ex. 4, p. 141; (4) Kent General Hospital, January 31, 2001 ("13 mo. old W [male] received varicella vaccination on 1/25/01. Following morning he had brief, generalized seizure * * * followed [by] another seizure * * * [had] seizures over weekend and mother notes several brief staring spells."), Ex. 6, p. 32; (5) Neurologist Dr. Stephen Falchek, March 1, 2001 ("Devon is a 14 month-old boy with an essentially benign medical history, who received a varicella and hemophilus influenza type B vaccination on 1/24/2001. Subsequent to that, on 1/25/2001, Devon experienced two seizures in the morning * * *."), Ex. 4, p. 137; (6) Dr. Andrea Catalano, immunologist, August 24, 2001 (Devon "has a history, at 13 months, after receiving his varicella and Prevnar immunization, had seizure activity approximately 21 hours after his immunizations were administered."), Ex. 4, p. 110; (7) Dr. Winston, October 23, 2001 ("He has a past medical history of a suspected seizure disorder, which began after his varicella immunization."), Ex. 4, p. 101; (8) Multi-Disciplinary Evaluation, May 7, 2002 ("He began to experience seizure-like activity at around the age of 12 months, reportedly after his 12 month immunizations were given by Dr. Winston. He has since had many different tests, and observational studies done to determine the etiology of the seizures. Thus far no definitive diagnosis has been given by neurologist--Dr. Stephen Falcheck.") Ex. 4, p. 69.

The other five excerpts require a bit more discussion. First, petitioner points to a notation from the records of Dr. Winston on July 25, 2001, in which it was noted that Devon was offered a Prevnar (pneumonia) vaccination on that date, but that such offer was "declined by mother [because]

of [reaction] [after] Prevnar & varicella.” (Ex. 4, p. 13.) This notation does imply that *Devon’s mother* believed that Devon’s seizures on January 25, 2001, constituted a “reaction” to either the Prevnar or varicella vaccinations that Devon had received on January 24, 2001, but it certainly does not demonstrate that *Dr. Winston* believed that the January 25 seizures were in reaction to the January 24 varicella vaccination.

Next, petitioner points to another notation in Dr. Winston’s records, made on July 31, 2001, in which Dr. Winston wrote that he “will report event to VAER[S].” (Ex. 4, p. 8.) However, the “event” in question was *not* Devon’s seizures on January 25, 2001, but rather Devon’s apparent seizures on July 26, 2001. Dr. Griesemer has never referred in this proceeding to the seizures of July 26, 2001, as relevant to his theory of causation in this case, so the fact that Dr. Winston agreed to report the July 26 seizures to VAERS (*i.e.*, the Vaccine Adverse Event Reporting System) seems wholly irrelevant to the causation question at issue here. (Moreover, petitioner failed to point out that, in the *very notation in question*, Dr. Winston actually seemed to express *doubt* that the seizures of July 26, 2001, were related to Devon’s vaccinations of the day before. The sentence written by Dr. Winston was as follows: “Although *I cannot conclude that most recent vaccine admin[istration] had [relationship] [with] present [seizures],*” nevertheless he “will report event to VAER[S].” (Ex. 4, p. 8, emphasis added.)

Petitioner also points out that when Devon was given a “Multi-Disciplinary Evaluation” on December 3, 2001, it was noted that Devon’s first seizure occurred 24 hours after an immunization, and that “[t]his has been reported as a possible adverse reaction to the immunization.” (Ex. 4, p. 93.) This notation in the “Health History” section of the record, however, indicates only that *whoever provided Devon’s history*, probably one of his parents, stated that the initial seizure was a “possible” adverse reaction to a vaccination. It certainly does not indicate that *any physician* had concluded that the initial seizure was vaccine-caused.

Similarly, petitioner notes that when Devon received a similar Multi-Disciplinary Evaluation on May 16, 2001, it was noted that Devon’s immunizations were not current “due to previous questionable reaction to vaccination.” (Ex. 4, p. 126.) But this notation indicates only that Devon’s parents or someone else found it “questionable” whether Devon’s initial seizure was a vaccine reaction. Again, it certainly does not indicate that *any physician* ever concluded that the initial seizure was vaccine-caused.

Finally, petitioner points to a record of a phone call apparently made by one of Devon’s parents when he had a *second* day of seizure-like activity, on January 27, 2001. (Ex. 4, p. 144.) The record indicates that the triage nurse who took the call (“Judy McReynolds, RN”) wrote the words “sounds like a severe, unusual reaction.” (*Id.*) First, it is not clear what the nurse thought was the cause of the “reaction.” Moreover, even assuming that she meant one of Devon’s vaccinations on January 24, 2001, this record still indicates only the immediate impression of one *nurse* that Devon’s seizures on January 25 and/or his seizures on January 27 resulted from one of his vaccinations on January 24. Once more, it certainly does not indicate that *any physician* ever concluded that Devon’s

seizures on January 27, 2001, or his seizures on January 25, 2001, or any other seizures, were vaccine-caused.

In sum, I have carefully reviewed the medical record notations cited by petitioner, but I find that they do *not* afford any substantial support to the petitioner's theory that the varicella vaccination caused, or contributed to, Devon's seizure disorder and/or developmental delay.²⁴

B. Other notations in the medical records

In fact, my overall review of Devon's medical records indicates that as to the causation question at issue in this case, the few relevant notations of Devon's treating physicians actually tend to support *respondent's view* of Devon's case, rather than petitioner's view. That is, while there are no notations in which a physician affirmatively indicates a view that Devon's conditions were *vaccine-caused*, there are a number of notations in which treating physicians indicated their view that the cause of Devon's condition is simply *unknown*.

For example, the first neurologist who treated Devon after his seizure onset, Dr. Carl Yacoub, wrote on January 30, 2001, that "I am uncertain as to what precipitated the seizures." (Ex. 4, p. 142.) On October 23, 2001, Dr. Bradley Winston, Devon's treating pediatrician, wrote that "any relationship" between Devon's seizures and his vaccinations "has not been established." (Ex. 4, p. 101.) On May 7, 2002, it was noted that "no definitive diagnosis" concerning the cause of the seizures "has been given by neurologist--Dr. Stephen Falchek," Devon's treating neurologist. (Ex. 4, p. 69.) And on August 24, 2001, Dr. Andrea Catalano, an immunologist, wrote that Devon's seizure disorder was "of unknown etiology."²⁵ (Ex. 4, p. 111.)

See also a notation recorded at a speech therapy evaluation on August 20, 2002, that the "cause of the seizure activity appears to be yet unknown." (Ex. 4, p. 48.) The opinion of the speech evaluator, of course, is of little importance, but the significance of this notation is that it indicates

²⁴To be sure, when a physician notes, in a medical record, the existence of a temporal relationship between a vaccination and a medical symptom, that physician may well be indicating a *question* in the physician's mind whether there is a causal relationship, or a *suspicion* that there might be a causal relationship. However, that is quite different from an indication that such physician has reached a *conclusion* concerning a causal relationship, or even believes such a relationship to be likely. In several Program opinions, judges and special masters have noted that the mere fact that a physician mentions a vaccination in a medical record, or notes that a symptom occurred soon after a vaccination, is *not* evidence that the physician causally attributed the symptom to the vaccination. *Moberly v. Secretary of HHS*, 85 Fed. Cl. 571, 604-05 (2009); *Caves v. Secretary of HHS*, No. 07-443V, slip op. at 8 (Fed. Cl. Spec. Mstr. Nov. 25, 2008); *Carter v. Secretary of HHS*, No. 04-1500V, 2007 WL 415185, at *22 (Fed. Cl. Spec. Mstr. Jan. 19, 2007).

²⁵"Etiology" in this context means "cause" or "origin." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 647 (30th ed. 2003).

that at that time Devon's parents were likely reporting to the evaluator that Devon's *treating physicians* considered the cause of his seizures to be "unknown."

In sum, cited above are four specific notations indicating that four of Devon's principal treating physicians considered the cause of his seizure disorder to be *unknown*. And there is also the fifth notation cited above, indicating *generally* that Devon's medical treaters did not profess to understand the cause of Devon's seizures. Therefore, I must conclude that, on balance, an analysis of the notations of Devon's treating physicians in the medical records actually adds support to the viewpoint of *respondent's* expert rather than to the theory of petitioner's expert.

IX

PETITIONER'S CASE FAILS THE *ALTHEN* TEST

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

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

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

A. Application of Althen Prongs 1 and 2 to this case

One interpretative 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 need 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. Secretary of HHS*, No. 01-60V, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. Secretary of HHS*, No. 96-518V, 2002 WL 31441212, at *18 n.42 (Fed. Cl. Spec. Mstr. Aug. 2, 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. Secretary of HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. Secretary of HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. Secretary of HHS*, No. 02-738V, 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. Secretary of HHS*, No. 06-120V, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30, 2008). And, most importantly, the *Federal Circuit itself* 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. Secretary of HHS*, 451 F.3d at 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.

A few decisions of judges and special masters have discussed issues with respect to the *precise* interpretation of Prongs 1 and 2 of *Althen*. *E.g., Doe 11*, 83 Fed. Cl. at 173-74; *Scott v. Secretary of HHS*, No. 03-2211V, 2006 WL 2559776, at *18 (Fed. Cl. Spec. Mstr. Aug. 21, 2006); *Nussman v. Secretary of HHS*, No. 99-500V, 2008 WL 449656, at *12-13 (Fed. Cl. Spec. Mstr. Jan. 31, 2008), *aff’d*, 83 Fed. Cl. 111 (2008); *Fields v. Secretary of HHS*, No. 02-311V, 2008 WL 2222141, at *7 n.5 (Fed. Cl. Spec. Mstr. May 14, 2008). However, it is *not* necessary, in this case, to delve into any such potential interpretative issues, since under any reasonable interpretation of *Althen*, the petitioner’s causation evidence put forward in this case could *not* satisfy either of the first two prongs of the *Althen* test.

That is, as set forth in detail above, I have concluded that petitioner has fallen short of demonstrating either that the varicella vaccine *can* contribute, in *general*, to the causation of seizures, or that an earlier onset of seizures, of the type that Devon suffered, *can* worsen a child’s developmental outcome, as Dr. Griesemer posited. I have also concluded that petitioner has failed to show that either of those outcomes *did* happen in Devon’s own case. Thus, petitioner’s causation arguments in this case would fail under virtually any interpretation of *Althen*’s Prongs 1 and 2.

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 the varicella vaccine contributed to the causation of *either* Devon’s seizure disorder or his developmental delay.

B. Application of Prong 3 of the Althen test to this case

Since I have concluded that the petitioner has failed to satisfy either of the *first two* prongs of *Althen*, it is not strictly necessary that I determine whether petitioner’s case satisfies the *third* prong. However, in the interest of completeness, I conclude that the petitioner has also failed to satisfy the third element of *Althen*.

The third prong of the *Althen* test, set forth above, requires “a showing of a proximate temporal relationship between vaccination and injury.” That is, under this third element of the *Althen* test, the petitioner would need to demonstrate that the first seizures of Devon’s seizure disorder occurred in a *time frame* that would be consistent with causation by the varicella vaccination in question.²⁶ The petitioner in this case, however, has failed to so demonstrate.

To be sure, this particular point does require explanation. At first glance, it would seem that the *most striking element* of petitioner’s causation case is that Devon’s first seizures did, in fact, take place less than 24 hours after his varicella vaccination of January 24, 2001. Doesn’t this striking fact by itself establish a “proximate temporal relationship,” as required under *Althen*? The answer to that question, though perhaps a surprising one, is “no.”

The problem for petitioner in this regard is that Dr. Griesemer wholly failed to explain at what time frame after vaccination he would *expect* a seizure caused by a varicella vaccination to occur. This is not surprising because, as noted above (pp. 7-16), Dr. Griesemer supplied no substantial evidence indicating that the varicella vaccination causes seizures *at any time*. To be sure, intuitively one might suppose that the fact that Devon experienced seizures within 24 hours after the vaccination indicates a connection. But, in fact, in those instances in which seizures *have* been found to be associated with other types of vaccinations, it is *not* necessarily the case that the associated seizures would occur *within 24 hours* after vaccination. For example, Dr. Snodgrass explained that medical scientists know that seizures are associated with two kinds of vaccinations, the old DTP vaccination (replaced in recent years by the DTaP vaccination) and the MMR vaccination. (Tr. 41.) In the case of DTP vaccinations, the increased risk of seizures was within the first 48 hours post-vaccination, but in the case of MMR the risk is *much later*, more than a week after vaccination. (*Id.*) Thus, if a seizure occurs one day after an MMR vaccination, it would *not* likely be caused by that vaccine, but a seizure occurring 10 days post-vaccination likely *would* be related. Therefore, since

²⁶In other words, the petitioner must demonstrate the existence of a “scientific temporal relationship” as discussed in *Pafford v. Secretary of HHS*, 64 Fed. Cl. 19, 29-30 (2005), *aff’d* 451 F.3d 1352 (Fed. Cir. 2006.) Or, as stated by the Federal Circuit, *Althen’s* third prong “requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *DeBazan v. Secretary of HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

we have no idea if the *varicella vaccine* has any association with increased seizure risk at *any* time, the fact that Devon experienced seizures about 24 hours post-vaccination really tells us nothing about whether those seizures were *vaccine-caused*.²⁷

In sum, the petitioner's case here certainly fails to satisfy the third element of *Althen* concerning a "proximate temporal relationship," as well. Therefore, having failed to satisfy *any* of the three *Althen* elements, it is clear that petitioner's causation theory fails under the test set forth in *Althen*.

X

DISCUSSION REGARDING "SIGNIFICANT AGGRAVATION"

Neither party to this case has suggested that the causation issue in this case should be analyzed under the concept of "significant aggravation." However, as noted above both experts have agreed that Devon likely did have a genetic defect that predisposed him to neurodevelopmental abnormalities. Accordingly, one could argue that petitioner's claim should be analyzed as a claim that Devon had a pre-existing condition that was "significantly aggravated" by his varicella vaccination. *See* § 300aa-11(c)(1)(C). However, even if this case were analyzed under the "significant aggravation" doctrine, the analysis and outcome would be the same. That is because when a petitioner asserts "significant aggravation" of a *non-Table* injury, the petitioner must still satisfy all three of the elements of the *Althen* standard.

Of course, if a petitioner claims a "significant aggravation" of a *Table Injury* (see discussion of the Vaccine Injury Table at p. 2 above), then a different test applies. *Whitecotton v. Secretary of HHS*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), on remand from *Shalala v. Whitecotton*, 514 U.S. 268 (1995). That test is especially designed to give the petitioner, when appropriate, the statutory *presumption* of causation inherent in a *Table Injury situation*.

However, where, as here, the vaccinee's underlying condition does *not* constitute a *Table Injury*, then no causation presumption applies, so the analysis is distinctly different from the *Whitecotton* analysis. One recent opinion explained that the proper analysis, for a claim that a

²⁷It is even conceivable that the timing of the seizures in this case might be considered as evidence that the seizures were *not* related to the varicella vaccination. That is, Dr. Snodgrass pointed out that the varicella vaccine is a *live virus* vaccine, more like the MMR vaccine than the DTP vaccine. (Tr. 83.) Thus, one might logically argue that, *if* the varicella vaccine *ever* causes seizures, it would more likely cause them *a number of days* later, like the MMR vaccine, rather than 24 hours later. There is no substantial evidence to justify such an inference with respect to Devon's case, but such an inference would seem to be at least as likely as Dr. Griesemer's suggestion that the occurrence of seizures one day post-vaccination supports a conclusion of vaccine causation. *See, e.g., DeBazan*, 539 F.3d at 1352-53 (affirming a special master's determination that the petitioner failed *Althen's* third prong because the onset of symptoms occurred *too soon* after vaccination to be vaccine-caused).

vaccinee suffered a “significant aggravation” of a *non-Table* condition, calls for a six-part test. *Loving v. Secretary of HHS*, 86 Fed. Cl. 135, 144 (2009). Under the first three parts of that test, in effect, the petitioner must demonstrate that the vaccinee’s post-vaccination condition was *significantly worse* than the vaccinee’s condition *prior* to vaccination. *Id.* Under the second three parts of that test, the petitioner must then demonstrate that such worsening of the vaccinee’s condition *meets the three prongs* of the *Althen* test, set forth above. *Id.*

In this case, I have already concluded, as set forth above, that Devon’s case does *not* meet the *Althen* criteria. Accordingly, even if one analyzed the petitioner’s claim in this case under the “significant aggravation” analysis, the petitioner would still fail to demonstrate a compensable claim in this case.

XI

DISCUSSION CONCERNING POST-HEARING PROCEDURES

The delay in resolving this case, subsequent to the hearing on December 18, 2006, is certainly unfortunate. In addition, the history of the post-hearing procedures conducted in this case is also quite unusual. In many cases under the Vaccine Act, subsequent to an evidentiary hearing there is a *briefing* process, but usually no post-hearing *evidentiary* filings. Further, it is very unusual that in this case the *special master* introduced several medical articles into the record. It is appropriate, therefore, that I briefly discuss the reasons for this unusual procedural history.

As noted above, the evidentiary hearing in this case took place on December 18, 2006. At the request of petitioner’s counsel, post-hearing briefs were then filed, with the last of those briefs filed on May 21, 2007. Accordingly, in August and September of 2007, I thoroughly reviewed the record of this case, in order to reach my ruling on the issue of “entitlement.” During that review, however, I found the record to be deficient in one important respect. Therefore, I issued an Order on September 17, 2007, in order to give both parties a chance to file medical literature mentioned by the experts but never filed.

In that Order, I noted that Dr. Griesemer had testified that he knew of “reports” in the medical literature indicating that the varicella vaccine sometimes causes seizures. (Tr. 16, 24.) He stated that “[t]he existence of seizures in response to varicella vaccine is established in the literature.” (Tr. 33.) In neither his report nor his testimony, however, did Dr. Griesemer cite to any examples of such literature. Petitioner’s counsel, in cross-examining Dr. Snodgrass, did refer to an unnamed “article” concerning post-licensure safety monitoring of the varicella vaccine, which indicated that some recipients of that vaccine experienced seizures at various times thereafter. (Tr. 68.) After I asked petitioner’s counsel about the article, counsel volunteered to file the article after the hearing (Tr. 71), and petitioner subsequently did file that article as Ex. 22. In my Order of September 17, 2007, however, I instructed petitioner’s counsel that if Dr. Griesemer was aware of any literature *other* than Ex. 22, supporting his assertion that the varicella vaccine causes seizures, petitioner should file that literature.

Similarly, in that Order of September 17, 2007, I also noted that Dr. Snodgrass had testified that he had reviewed studies concerning the varicella vaccine, conducted *prior* to the licensure of the vaccine, which involved comparing vaccinated individuals against non-vaccinated individuals. Respondent, however, had not filed any literature describing such studies. Accordingly, in my Order I instructed respondent that if any such literature existed, respondent should file it.

In response to my Order of September 17, 2007, and a follow-up Order filed on October 25, 2007, petitioner filed Ex. 23, while respondent filed Exs. C and D. However, those documents still did not seem to match the descriptions of supposedly-existing literature stated by the two experts during the hearing. Therefore, I instructed my law clerk to perform a medical literature search, which turned up several items of possible relevance to this case. That literature, identified by my clerk, was attached to an Order filed on February 5, 2008, described as Special Master's Exhibits 1 through 5.

On February 4, 2008, I conducted an unrecorded telephonic status conference, in order to make the parties aware of that literature, and to request that the parties provide additional testimony from their experts during a supplemental telephonic hearing. At the conference, however, both counsel responded that they would prefer to have their experts address *in writing* the recently-filed medical literature, rather than have a second evidentiary hearing. Accordingly, I instructed each party to file a supplemental report from its expert, addressing the items of medical literature filed since the evidentiary hearing. In response, in March of 2008 petitioner filed Ex. 24, a supplemental report of Dr. Griesemer, while respondent filed Ex. E, a supplemental report of Dr. Snodgrass.

After reviewing those supplemental expert reports, I conducted an additional telephonic status conference on April 2, 2008, followed by my Order issued later that day. As explained in that Order, I instructed the parties to have their experts address one more aspect of the post-hearing medical literature. On May 9, 2008, respondent filed Ex. I, another report of Dr. Snodgrass, and on July 3, 2008, petitioners filed Ex. 25, a further expert report of Dr. Griesemer. Those items completed the evidentiary record in the case.

Thus, the reason why I instructed the parties after the hearing to file medical literature, and later to file supplemental expert reports, should be clear from the above description of the post-hearing proceedings. As noted, after the last post-hearing brief was filed, when I reviewed the record in order to write my entitlement ruling, I found the record to be very unsatisfactory. That is, each of the two experts had testified that he was basing his opinion on certain reports contained in medical literature. Dr. Griesemer stated that reports showed that the varicella vaccine can cause seizures, while Dr. Snodgrass described reports showing the *exact opposite*. Clearly, the outcome of the case depended in significant part upon which expert's testimony was accurate in this regard. So, I concluded that I had no reasonable choice but to ask the parties to supply the literature that their experts had described. Then, when the documents filed by the parties in response to my 2007 post-hearing orders still did not seem to match *either* expert's earlier descriptions of supposedly-existing literature, I instructed my law clerk to perform a medical literature search. And when that search

turned up several items which seemed to be possibly relevant, I filed that literature into the record of this case, asking the experts to comment thereupon.

It is not particularly unusual for a special master to request, after a hearing, that a party file literature that was discussed at the hearing but not previously filed. *See, e.g., Lee v. Secretary of HHS*, No. 03-2479V, 2005 WL 1125672, at *10 (Fed. Cl. Spec. Mstr. Apr. 8, 2005). It is certainly more unusual for a special master to introduce medical literature into the record. However, such introduction of evidence by a special master is certainly authorized under the Vaccine Act,²⁸ and is certainly appropriate when, as here, the special master gives the parties a full and fair chance to respond to any evidence introduced by the special master. In any event, my own introduction in this case of the “special master’s exhibits” turned out to be of no import, because neither expert thereafter indicated any reliance on such articles in their supplemental expert reports, so that I have placed *no reliance* on those articles in reaching my conclusion in this case.

Of course, as a result of my requests for additional literature and expert reports, the resolution of this case was delayed, and that is unfortunate. I must note, however, that the primary cause of most of the delay was, in my view, the failures of the attorneys and experts for *both* parties to file, *prior* to the evidentiary hearing, those exhibits that the parties eventually filed *after* the hearing. In this case, *both* experts came into the hearing and based their testimony *explicitly* on the contents of allegedly-existing medical literature. Yet no such literature was filed before or at the hearing. Clearly, both counsel, as well as the experts, erred in this regard. Both counsel, veterans of Vaccine Act litigation, should have been aware of how their experts were going to testify, and should have recognized that the outcome of this case would depend heavily on the unfiled literature on which each expert based his testimony. Clearly, both counsel should have caused the appropriate literature to be filed before the evidentiary hearing--indeed, such literature probably should have been filed at or near the time of the filing of each expert’s initial written report. The failure of both counsel to do so is certainly the primary reason for the unfortunate delay between the hearing and this Decision.

However, I must also acknowledge my own responsibility for additional delay, once the last of the parties’ post-hearing documents was filed in July of 2008. At that point, I was engaged in the task of preparing the decision in the autism “test case” which was eventually filed as *Cedillo v. Secretary of HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009). Because of the extreme importance of that case and the large number of families who would be potentially affected by that *Cedillo* ruling, I found it appropriate to postpone my return to this case until I

²⁸Congress gave the Vaccine Act special masters broad discretion in deciding how to accept evidence. (*See, e.g.,* § 300aa-12(d)(3)(B).) Congress specified that a special master should be “vigorous and diligent in *investigating*” Program factual issues (H.R. Rept. No. 99-908, at 17 (1986) *reprinted in* 1986 U.S.C.C.A.N. 6344, 6358 (emphasis added)), in an “inquisitorial” fashion (H.R. Rept. No. 101-247, at 513 (1989) *reprinted in* 1989 U.S.C.C.A.N. 1906, 2239). That language indicates that a special master may actively seek out evidence beyond that presented by the parties in a particular case. Thus, while it is relatively rare for a special master to utilize that authority to seek out additional evidence, such authority clearly does exist under the statute.

completed that ruling. I still believe that was an appropriate utilization of my time, given the circumstances. However, I recognize that it was unfortunate that the Staplefords had to wait several additional months for this Decision, and I regret that I was not able to complete this Decision sooner.

Finally, I add that the post-hearing delay did *not* change the outcome of the case. Had I been required to issue a ruling directly after the filing of the last post-hearing brief in May of 2007, before any documents had been filed in response to my post-hearing Orders, such ruling would have been to deny the petitioner's claim. At that point in time, as now, I viewed the theories of Dr. Griesemer to be speculative, and devoid of substantial evidentiary support.

XII

CONCLUSION

The record of this case demonstrates plainly that Devon Stapleford and his family have been through a tragic and painful ordeal. The entire family is certainly deserving of great sympathy. Congress, however, designed the Program to compensate only the families of individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or causation-in-fact evidence, to a listed vaccine. In this case, as described above, no such link has been demonstrated. Accordingly, I conclude that the petitioner in this case is *not* entitled to a Program award.²⁹

/s/ George L. Hastings, Jr.

George L. Hastings, Jr.
Special Master

²⁹In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.