

In the United States Court of Federal Claims

No. 10-272V

This Opinion Will Not Be Published in the U.S. Court of Federal Claims Reporter Because It Does Not Add Significantly to the Body of Law.

(Filed Under Seal: May 18, 2015)

Reissued: June 9, 2015¹

NATALIE ROWAN,	*
	*
Petitioner,	*
	*
v.	*
	*
SECRETARY OF HEALTH AND	*
HUMAN SERVICES,	*
	*
Respondent.	*

OPINION

ALLEGRA, Judge:

Petitioner, Natalie Rowan (petitioner), seeks review of a decision issued by a special master denying her vaccination injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to 300aa-34 (2006), alleging that she suffered injuries including headaches, abdominal pain, and difficulty walking brought about by the Human Papillomavirus (HPV) vaccine. On review, Special Master Nora Beth Dorsey denied compensation, finding that Ms. Rowan’s illness was not attributable to her receiving the HPV vaccine. For the reasons that follow, this court affirms that decision.

I. BACKGROUND

A brief recitation of the facts provides necessary context.

¹ An unredacted version of this opinion was issued under seal on May 18, 2015. The parties were given an opportunity to propose redactions, but no such proposals were made. Nevertheless, the court has incorporated some minor changes into this opinion.

Petitioner was born on October 11, 1995. Other than asthma, Ms. Rowan was a healthy child. In 2005, she began complaining of headaches. On December 7, 2005, those headaches were associated with an upper respiratory infection; two years later, on March 6, 2007, the headaches were associated with abdominal pain and strep pharyngitis.

On August 21, 2007, Ms. Rowan received her first of three HPV vaccines from her primary care provider, Dr. Joanne Fogarty. She reported no adverse effects after this vaccination. On November 12, 2007, Ms. Rowan received her second HPV vaccination. On November 21, 2007, petitioner complained to Dr. Fogarty of a headache and stomach ache, and was diagnosed with a viral syndrome. On May 15, 2008, Ms. Rowan visited Dr. Fogarty again, complaining of "headaches since Monday." Dr. Fogarty's notes indicate that Ms. Rowan's menses had begun two months prior, and that her father had a history of migraines. On July 14, 2008, Ms. Rowan received her third and final HPV vaccination.

On September 24, 2008, Ms. Rowan visited Dr. Fogarty, complaining of a sore throat, and was diagnosed with pharyngitis. Dr. Fogarty also noted Ms. Rowan's prior history of headaches. On October 20, 2008, petitioner saw Dr. Fogarty again, complaining of a sore throat, continued nasal congestion, and increased fatigue. On October 28, 2008, Ms. Rowan complained of an ongoing headache, and again on November 3, 2008, and November 14, 2008.

On December 30, 2008, Ms. Rowan visited Dr. Karen Powers, a neurologist. Her father described to Dr. Powers that Ms. Rowan had a history of migraines beginning with her first menstrual cycle in March of 2008. Ms. Rowan's father also indicated that since October of 2008, Ms. Rowan was complaining of headaches, and the severity of the headaches was causing his daughter to miss school. Dr. Powers diagnosed Ms. Rowan with chronic daily headache.

In May of 2009, Ms. Rowan's father filed a Vaccine Adverse Event Reporting System (VAERS) report on behalf of Ms. Rowan. Later that year, Ms. Rowan continued to visit Dr. Fogarty, complaining of headaches. She visited other doctors regarding her headaches, including doctors at the Albany Medical Center, Dr. Charles Argoff, and Dr. Joanne Porter, a pediatric hematologist. In January of 2010, Ms. Rowan visited Dr. Powers again, whose notes indicate that Ms. Rowan's symptoms had "evolved into multiple somatic complaints of headache, leg weakness, difficulty walking, gastrointestinal pain, and what appears to be depression."

Over time, Ms. Rowan saw numerous physicians, including neurologists, an infectious disease specialist, a physical medicine rehabilitation specialist, a pain management specialist, a hematologist and oncologist, and a Lyme disease specialist. Ms. Rowan underwent numerous tests and evaluations, including a negative Lyme test and cervical spine x-ray, as well as the following tests that proved normal: a sinus and head computerized tomography (CT) scan, a magnetic resonance imaging (MRI) of the brain, a magnetic resonance (MR) angiography of the head, a MR venogram of the head, a MRI of the spine, an electromyography (EMG), and lab results from a lumbar puncture. Her doctors prescribed a variety of drugs, including Imitrex, Fiorcet, Topamax, naproxen, hydrocodone, butalbital APAP, and cyclobenzaprine. None provided any relief. By March of 2010, Ms. Rowan was limited to a wheelchair, unable to walk on her own.

In the summer of 2010, Ms. Rowan's father obtained advice from Lloyd Phillips, an attorney, who had been referred by another parent who alleged her daughter had been injured by the HPV vaccine. Mr. Phillips recommended an extensive vitamin regimen and a specialized diet. Ms. Rowan followed Mr. Phillips' recommendations, and within a matter of weeks, her condition was improving. By the middle of 2011, Ms. Rowan was "like her old self."

On May 3, 2010, Ms. Rowan's father filed a petition on her behalf against the Secretary of Health and Human Services.² On January 14-16, 2014, an entitlement hearing was held in front of Special Master Dorsey. At that hearing, Ms. Rowan's expert witness, Dr. Yehuda Shoenfeld, argued that she was affected by Autoimmune Syndrome Induced by Adjuvants (ASIA), the "chronic stimulation of the immune system" which causes autoimmune disease. Dr. Shoenfeld testified that in some patients experiencing ASIA, adverse reactions can occur after days, weeks, or years. By comparison, respondent put forth three expert witnesses: (i) Dr. James L. Whitton testified that ASIA is not a generally accepted medical theory and that aluminum adjuvants do not cause injury; (ii) Dr. Edward W. Cetaruk testified regarding the safety of aluminum as an adjuvant and how aluminum functions in the human body; and (iii) Dr. Stephen J. McGeady testified that the HPV vaccine did not cause Ms. Rowan's injuries, as her headaches pre-dated her receipt of the HPV vaccine, her diagnostic tests were normal, and there was no evidence of her having an autoimmune disease. Dr. McGeady additionally testified that the temporal relationship between Ms. Rowan's vaccinations and her symptoms was no indication that the vaccine caused her injury.³

On December 8, 2014, the special master issued an opinion denying compensation.⁴ The special master found that Ms. Rowan was treated for, and diagnosed with, headaches, but she had not presented preponderant evidence of chronic fatigue syndrome or any other injury. The special master found that Dr. Shoenfeld "failed to provide persuasive or reliable evidence to support his [ASIA] theory" and had conceded the ASIA theory is not proven and relied upon faulty medical studies. The special master likewise found it persuasive that none of Ms. Rowan's physicians had diagnosed her with symptoms of aluminum toxicity, there was no evidence of chronic stimulation of her immune system, her diagnostic tests were primarily normal, and her condition did not progress to an autoimmune disease. In addition, the special master found a temporal relationship of "days to weeks to years," was not a medically appropriate timeframe. Based on the foregoing, the special master concluded that Ms. Rowan had not proven that the vaccine had caused her injury.

² The petition was later amended when petitioner reached the age of majority.

³ None of the physicians providing evidence and testimony in this case treated or examined petitioner.

⁴ The special master issued a published version of the opinion on December 30, 2014. *See Rowan v. Sec'y of Health & Human Servs.*, 2014 WL 7465661 (Fed. Cl. Dec. 8, 2014).

On January 7, 2015, petitioner filed a timely motion for review of the special master's decision denying compensation. On February 4, 2015, respondent filed its response to the motion. Argument on this motion is unnecessary.

II. DISCUSSION

Under the Vaccine Act, this court may review a special master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). In that instance, the court may: "(A) uphold the findings of fact and conclusions of law . . . ; (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or; (C) remand the petition to the special master for further action in accordance with the court's direction." *Id.* at § 300aa-12(e)(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an "arbitrary and capricious" standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992); *Doyle ex rel. Doyle v. Sec'y of Health & Human Servs.*, 92 Fed. Cl. 1, 5 (2010).⁵ Under the arbitrary and capricious standard, "reversible error is 'extremely difficult to demonstrate' if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'" *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (citing *Hines ex rel. Sevier v. Sec'y of Dep't of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)).

The preponderance standard requires a petitioner to demonstrate that it is "more likely than not" that the vaccine at issue caused her injury. *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), *cert. denied*, 551 U.S. 1102 (2007). To determine if the petitioner has carried her burden, the special master must assess "the record as a whole" and may not make an entitlement decision in her favor based solely on her own claims "unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). It is the special master in vaccine cases who weighs "the persuasiveness of particular evidence . . . [and] assess[es] the reliability of testimony, including expert testimony." *Moberly*, 592 F.3d at 1325; *see also Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 120 Fed. Cl. 102, 106 (2015).

Petitioner seeks recovery in this case for an "off-Table" injury, that is, an injury caused by a vaccine other than those injuries listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a). In off-Table injuries, claimants must show causation in fact by a preponderance of the

⁵ *See also Saunders v. Sec'y of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994); *Savin ex rel. Savin v. Sec'y of Health & Human Servs.*, 85 Fed. Cl. 313, 315 (2008). Similar principles apply to this court's review of findings made by special masters in rulings on a motion for relief from judgment under RCFC 60. *See* RCFC App. B, Vaccine Rule 36(b)(7).

evidence. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A); *see also Moberly*, 592 F.3d at 1321. The Federal Circuit summarized the claimant’s evidentiary burden associated with off-Table cases in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), holding that she must establish by preponderant evidence:

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

These factors are now commonly referred to as the three *Althen* prongs. *See Moriarty*, 120 Fed. Cl. at 105; *Deribeaux ex rel. Deribeaux v. Sec’y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013); *Mosley v. Sec’y of Health & Human Servs.*, 119 Fed. Cl. 734, 742 (2015).

The special master found petitioner failed to establish any of the three *Althen* prongs by preponderant evidence. Petitioner challenges all three of these determinations. Causation in fact is proved by a petitioner who satisfies each of the *Althen* factors by preponderant evidence. *Althen*, 418 F.3d at 1278; *see also Shyface*, 165 F.3d at 1352-53; *Hirmiz v. Sec’y of Health & Human Servs.*, 119 Fed. Cl. 209, 216 (2014). Expanding on these criteria for establishing causation, the Federal Circuit stated that “[a] persuasive medical theory is demonstrated by proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury, the logical sequence being 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 (citation omitted) (internal quotations omitted); *see also Hirmiz*, 119 Fed. Cl. at 216.

In proving the first *Althen* prong, a petitioner must demonstrate a medical theory that is “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 (quoting *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)); *see also Simanski v. Sec’y of Health & Human Servs.*, 671 F.3d 1368, 1384 (Fed. Cir. 2012). “Although . . . a medical theory may be supported by expert medical testimony, the mere existence of such testimony is insufficient to satisfy the burden of showing a ‘persuasive’ medical theory – this theory must also preponderate.” *Taylor v. Sec’y of Health & Human Servs.*, 108 Fed. Cl. 807, 819 (2013).⁶ Once the petitioner has made a *prima facie* case of causation, “the burden shifts to the government to prove by a preponderance of the evidence that the petitioner’s injury is due to factors unrelated to the administration of the vaccine” *de Bazan v. Sec’y of Health &*

⁶ *See also Languard v. Sec’y of Health & Human Servs.*, 109 Fed. Cl. 421, 441 (2013) (a reputable medical or scientific explanation “may require an explanation of the steps by which the vaccination was believed to result in the harm, so that what was actually observed by treating physicians may be compared to the posited process and the appropriateness of the time frame involved could be determined”).

Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008) (citation omitted) (internal quotation omitted). Here, however, the evidence plainly indicated that petitioner did not demonstrate that a medical theory supported her case.

The special master determined that “Dr. Shoenfeld failed to provide persuasive or reliable evidence to support his theory.” Petitioner asserts Dr. Shoenfeld’s “ASIA” theory – that the aluminum adjuvants in the HPV vaccine brought on petitioner’s illness – is medically accepted and a plausible theory for how the HPV vaccine caused petitioner’s injuries. But, the special master found that Dr. Shoenfeld was unable to explain adequately how the ASIA theory functions. For example, Dr. Shoenfeld was unable to explain whether the aluminum-adjuvant or the virus-like particles in the vaccine cause injury.⁷ He conceded that ASIA is not a proven theory – and respondent’s expert, Dr. Whitton, persuasively testified regarding the safety of aluminum adjuvants while refuting a number of Dr. Shoenfeld’s contentions. Dr. Cetaruk corroborated critical aspects of Dr. Whitton’s testimony regarding the safety of aluminum in the human body and how the aluminum in an adjuvant is excreted naturally from the body.

Petitioner asserts that Dr. Cetaruk was unqualified to assess Dr. Shoenfeld’s medical theory because Dr. Cetaruk never published in the field of vaccine injury. The record, however, indicates otherwise. The special master’s role, as the factfinder, is to weigh the evidence and assess the testimony, including the credibility of the expert witnesses. In vaccine cases, like any other case involving an expert witness, “[a]ssessments as to the reliability of expert testimony often turn on credibility determinations, particularly . . . where there is little supporting evidence for the expert’s opinion.” *Moberly*, 592 F.3d at 1325-26; *see also de Bazan*, 539 F.3d at 1353-54; *Pafford*, 451 F.3d at 1359. Special masters in vaccine cases “are entitled – indeed, expected – to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.” *Moberly*, 592 F.3d at 1326. The court finds that the special master assessed the evidence and the expert testimony, and articulated a rational basis for her decision.

Petitioner argues that defendant’s expert witnesses were not qualified to critique Dr. Shoenfeld’s theory because neither Dr. Cetaruk nor Dr. Whitton reviewed Ms. Rowan’s medical records, and thus were “not in the best position to make a determination whether Dr. Shoenfeld’s theory is credible.” But, in arguing otherwise, petitioner totally confuses the first and second *Althen* prongs. The first prong, the medical theory prong, requires a showing of general causation. *See Veryzer v. Sec’y of Health & Human Servs.*, 100 Fed. Cl. 344, 352 (2011), *aff’d*, 475 Fed. Appx. 765 (Fed. Cir. 2012); *Contreras v. Sec’y of Health & Human Servs.*, 2015 WL 2124751, at *14 (Fed. Cl. May 6, 2015). General causation is not petitioner specific, but rather is a “medical theory causally connecting the vaccination and the injury,” as *Althen* describes. Thus, in refuting Dr. Shoenfeld’s ASIA theory, respondent’s expert witnesses did not have to

⁷ The special master found that Dr. Shoenfeld relied upon several studies that did not support his medical theory. One of those studies was the Reeves study. The adjuvant in that study was not aluminum, but rather pristane, a toxic substance. Other studies involving aluminum adjuvants focused on serious neurological side effects. Petitioner, however, did not seek compensation for a vaccine-related neurological disorder.

review petitioner's medical records. Dr. McGeady, respondent's expert for the second *Althen* prong, *did* review petitioner's medical records. Thus, the fact that Drs. Cetaruk and Whitton did not review petitioner's medical records provided no basis for the special master to discredit their testimony or for this court to find that her determination was arbitrary, capricious, or contrary to law.

Turning to *Althen's* second prong, the court next must consider whether there was "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" by a preponderance of the evidence. *Althen*, 418 F.3d at 1278; *see also Deribeaux*, 717 F.3d at 1367; *Pafford*, 451 F.3d at 1355. In order to prevail on this prong, the petitioner must show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Althen* (quoting *Shyface*, 165 F.3d at 1352). In *Capizzano v. Secretary of Health & Human Services*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the Federal Circuit stated, "[a] logical sequence of cause and effect' means what it sounds like – the claimant's theory of cause and effect must be logical. Congress required that, to recover under the Vaccine Act, a claimant must prove by a preponderance of the evidence that the vaccine caused his or her injury." *See also Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 439 (2014), *aff'd*, 2015 WL 795060 (Fed. Cir. Feb. 26, 2015); *Isaac v. Sec'y of Health & Human Servs.*, 108 Fed. Cl. 743, 765, *aff'd*, 540 Fed. Appx. 999 (Fed. Cir. 2013).

The special master found that petitioner did not show preponderant evidence that the HPV vaccine caused her injury. The special master focused on petitioner's lack of an adjuvant-induced illness. But, petitioner exhibited no symptoms of aluminum toxicity and she showed no evidence of macrophagic myofasciitis syndrome (MMF).⁸ Importantly, none of her doctors diagnosed her with any adjuvant-induced illness or chronic fatigue syndrome.⁹ Not one of petitioner's many physicians attributed her illness to the HPV vaccine.

Dr. Shoenfeld's medical theory is predicated on the idea that an individual experiencing ASIA suffers from an autoimmune disorder. According to Dr. Shoenfeld, in order to "develop autoimmune disease or chronic fatigue," an individual must have a genetic predisposition to develop that condition. Petitioner attempts to argue that she must have had a genetic predisposition because she "clearly developed a genetic disease." However, the evidence does not support this – none of the evidence showed that she was genetically predisposed to developing an autoimmune disorder.¹⁰ Dr. Shoenfeld contended that this was indicative of

⁸ In a study Dr. Shoenfeld relied upon, individuals who received an aluminum adjuvant suffered from MMF. Ms. Rowan did not have MMF, nor did she exhibit any lesion that is typical on patients who have MMF and have received aluminum adjuvants.

⁹ For purposes of *Althen's* second prong, petitioner argues that she developed a genetic disease, specifically chronic fatigue syndrome. However, in her injury determination, the special master found that petitioner had not presented preponderant evidence of chronic fatigue syndrome.

¹⁰ The vast majority of diagnostic tests were normal. The one abnormality was a white blood cell count of 3.2, with elevated lymphocytes in September of 2009.

stimulation of petitioner's immune system as a result of the vaccination, while Dr. McGeady determined that the results were because of a viral infection. The special master found Dr. McGeady's explanation more credible. The court finds no reason why the special master's finding is arbitrary or capricious.

Finally, insofar as the last of the *Althen* factors applies, petitioner must demonstrate, by a preponderance of evidence, "a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278; *see also Contreras*, 2015 WL 2124751, at *12. The Federal Circuit emphasized the importance of a temporal relationship in *Pafford*, 451 F.3d at 1358, when it noted that, "without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm." *See also Mosley*, 119 Fed. Cl. at 742. Requiring evidence of strong temporal linkage is consistent with the third requirement articulated in *Althen* because "[e]vidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis." *Pafford*, 451 F.3d at 1358 (citing *Capizzano*, 440 F.3d at 1326).¹¹

In this regard, the special master found that Dr. Shoenfeld "failed to provide a medically appropriate timeframe for onset given his proposed theory." For his medical theory, Dr. Shoenfeld contends that days, months or years – essentially any amount of time between vaccination and onset of symptoms – is consistent with his medical theory. Yet, the special master found that Dr. Shoenfeld was unable to offer any real support for his opinion. According to Dr. Shoenfeld, patients with ASIA typically experience an immediate allergic reaction to the vaccine, followed by chronic stimulation of the immune system. The special master found that

¹¹ The Federal Circuit further adumbrated,

[i]f, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor. Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury.

Pafford, 451 F.3d. at 1358; *see also Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1150 (Fed. Cir. 2007); *Simanski*, 115 Fed. Cl. at 440; *Isaac*, 108 Fed. Cl. at 765.

petitioner did not experience an allergic reaction to her first or second vaccination. Dr. Shoenfeld was unable to explain this inconsistency with his medical theory.

Instead, petitioner offers no reason why the special master erred. Rather, petitioner argues that the adjuvant, and the toxicity, in petitioner's body amassed as she received the second and third vaccinations, leading to headaches of a "totally different scope and character" than the ones petitioner experienced before receiving the vaccine. The special master determined that Dr. Shoenfeld gave no explanation why the onset of ASIA is so variable, and why a timeframe of three months, in petitioner's case, was appropriate. While the court does not disagree that Ms. Rowan had severe headaches around the time she was receiving the HPV vaccine, this is no reason to disturb the special master's finding.

Petitioner was required to show the special master erred in her findings on all three of the *Althen* prongs. The court finds no such error, and thus need go no further. Applying the pertinent evidentiary standard, the court concludes that the special master's findings were supported by substantial evidence and were neither arbitrary or an abuse of discretion.

III. CONCLUSION

The court will not gild the lily. For the reasons stated, the court **DENIES** petitioner's motion for review. The decision of the special master is sustained. The Clerk's Office is directed to enter **FINAL JUDGMENT** in accordance with the special master's decision of December 8, 2014.¹²

IT IS SO ORDERED.

s/Francis M. Allegra

Francis M. Allegra

Judge

¹² This opinion shall be unsealed, as issued, after June 1, 2015, unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to that date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons therefor.