



Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>3</sup> (“Program”), on behalf of their son, W.D.W. Petition (“Pet”) at 1. Petitioners filed Amended Petitions in this case and ultimately alleged in the Fourth Amended Petition that W.D.W. suffered an adverse reaction as a result of an initial hepatitis B vaccine he received on December 9, 1997, as well as other subsequent vaccines he received, “especially the DtaP, HIB, and Hep-B vaccines he received on June 10, 1998.” Fourth Amended Pet. at 5. Petitioners specifically argue that with each successive set of vaccines W.D.W. received, he suffered “adverse reactions, multiple physical and health problems and injuries such as fever, nausea, pain, irritability, loss of appetite, fatigue, tiredness, diarrhea, pain, inflammation, swelling and redness at injection site, as well as severe allergic reactions such as significant rashes and hives on his body, difficulty breathing, pain, etc...” *Id.* Petitioners also allege that in the alternative, W.D.W. “suffered an aggravation of a pre-existing medical condition (weakened immune system and intolerance to vaccines) as a result of said vaccines.” *Id.* at 8.

After a review of the petition and supporting documents, Respondent’s counsel filed a “Motion To Dismiss For Failure to Prosecute,” asserting that W.D.W.’s records do not demonstrate a causal association between his vaccines and alleged injuries; additionally, Respondent argued that Petitioners have not provided a medical expert report addressing their burden under *Althen*, and the case has been pending for almost 13 years. Resp’t’s Motion at 7, ECF No.76. Respondent requests that the undersigned dismiss the above-captioned petition. *Id.* Petitioners did not oppose Respondent’s Motion; this case is now ripe for decision.

## I

### PROCEDURAL HISTORY

On December 8, 2000, Petitioners filed a petition for vaccine compensation along with the Affidavit of Brian R. Arnold, Attorney, and medical records labeled Exhibits 1 through 12.<sup>4</sup> Petitioners alleged that W.D.W. suffered mercury poisoning as a result of a

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<sup>3</sup> National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42. U.S.C. §300aa (2006).

<sup>4</sup> Documents accompanying the petition were filed in the following order: Exhibit 1- Affidavit of Brian R. Arnold, Attorney for Petitioner, Prenatal Records, Exhibit 2-Dr. Kuhl’s Pediatrician Records, Exhibit 3-Normal Regional Hospital Records-Darius, Exhibit 4-Normal Regional Hospital-Roxan, Exhibit 5-Marshall Regional Hospital, Exhibit 6- Shawnee Regional Hospital Records, Exhibit 7-Sooner Start Program, Exhibit 8-Texas’ Early Childhood Intervention Program, Exhibit 9-Harrison County Co-op,

hepatitis B vaccination W.D.W. received within 24 hours of his delivery on December 9, 1997, as well as subsequent vaccines that he received.<sup>5</sup> Pet. at 2-4. The case was assigned to Chief Special Master Golkiewicz. Notice of Assignment, ECF No. 2. Respondent's counsel, Traci R. Manning, made an appearance on December 19, 2000. Notice, ECF No. 4.

Special Master Golkiewicz issued an Order on January 31, 2001, directing Petitioners to file the expert report and curriculum vitae ("CV") of Dr. Holmes, Petitioner's expert, or to file a status report by March 2, 2001. Order, ECF No. 5. On March 20, 2001, April 24, 2001, May 14, 2001, June 20, 2001, August 8, 2001, August 22, 2001, October 9, 2001, and February 4, 2002, Petitioners filed status reports regarding their status in retaining an expert. Filings, ECF Nos. 7-14. No expert report was filed on any of the above-mentioned dates.

On May 13, 2002, Chief Special Master Golkiewicz issued an Order stating that a committee of petitioners' counsel, respondent's representatives, and special masters had been formed to determine how to most efficiently process autism/thimerosal injury cases, and pursuant to the agreement of that committee, the Petitioners in this particular case could delay indefinitely the filing of medical records relating to this case until the committee determined a procedure for resolving the general "causation" issue involved in these related cases. Order, ECF No. 17. Additionally, Chief Special Master Golkiewicz suspended the filing of Respondent's Rule 4(c) Report. *Id.*

On July 29, 2002, the case was reassigned to Special Master Hastings. Order, ECF No. 19. On this same date, Petitioners opted to join the Omnibus Autism Proceeding ("OAP"), and a stay was issued, "pending the completion of a general inquiry by the Office of Special Masters regarding the possible causal relationship between certain vaccinations and autistic spectrum disorders ("ASDs")." Order at 1, July 29, 2002.

On February 5, 2007, the case was reassigned to Special Master Campbell-Smith. Order, ECF No. 21. Special Master Campbell-Smith ordered, on January 15, 2008, that Petitioners file within 90 days all medical records from the period of the vaccinee's birth through either, whichever date was later, the date of petition filing or the date of the vaccinee's initial diagnosis of autism, autism spectrum disorder, a speech or language delay related to an autism diagnosis, or any similar neurological disorder related to an

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Exhibit 10-Oklahoma Hearing Evaluation, Exhibit 11-Oklahoma Eye Exam, Exhibit 12-Dr. Amy Holmes & Dr. Stephanie F. Cave Medical Records-Mercury Removal.

<sup>5</sup> Additional vaccines cited in the original petition are as follows: DTaP, Hib, Hep-B, and OPV administered on February 16, 1998, DTaP, Hib, OPV administered on April 9, 1998, DTaP, Hib, and Hep-B administered on June 10, 1998, and MMR administered on July 7, 1999. Pet. at 1-3.

autism diagnosis; Respondent would then have 45 days, subsequent to Petitioners' filings, to file a Statement Regarding whether the Claim should Proceed in the OAP. Order, ECF No. 22.

Respondent's counsel filed a "Statement Regarding Jurisdiction and Appropriateness of Proceeding within the Omnibus Autism Proceeding" on June 2, 2008. Statement, ECF No. 24. Respondent noted that the record indicated that this case was filed prior to the expiration of the relevant statutory limitations period, and involved a diagnosis of autism spectrum disorder; therefore, Respondent did not oppose further processing of this case in the Court's Omnibus Autism Proceeding. *Id.* at 3.

The OAP was ongoing for several years, and has been summarized in Program decisions as follows:

Ultimately, the Petitioners' Steering Committee ["PSC"], an organization formed by attorneys representing petitioners in the OAP, litigated six test cases presenting two different theories on the causation of ASDs. The first theory alleged that the measles portion of the measles, mumps, rubella vaccine could cause ASDs.<sup>6</sup> That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that mercury contained in thimerosal-containing vaccines could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008. Decisions in each of the three test cases pertaining to the PSC's first theory rejected the petitioners' causation theories. *Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

Decisions in each of the three "test cases" pertaining to the PSC's second theory also rejected the petitioners' causation theories, and petitioners in each of the three cases chose not to appeal. *Dwyer v.*

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<sup>6</sup> Other decisions have described the first theory as follows: "The MMR vaccine and thimerosal-containing vaccines can *combine* to cause autism." *King v. Sec'y of Health & Human Servs.*, 2010 WL 892296, at \*8; *see also* Order, Mar. 15, 2010 at 1-2.

*Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). Thus, the proceedings in these six test cases are concluded.

*See Douglass v. Sec'y of Health & Human Servs.*, No. 04-427V, 2012 WL 2108883, at \*1 (Fed. Cl. Spec. Mstr. Apr. 10, 2012) (footnote omitted).

On February 2, 2011, Special Master Campbell-Smith ordered that Petitioners file an Amended Petition that was fully compliant with §§ 300aa-11(c) and which clearly explained the theory of vaccine causation in this case. Order, ECF No. 26. Petitioners filed their Amended Petition on March 2, 2011. Amended Pet., ECF No. 27. The Amended Petition alleged that W.D.W. sustained a “Table Injury” as a result of the Hep-B vaccine he received as well as other subsequent vaccines listed in the petition. *Id.*

On August 4, 2011, Respondent’s counsel issued a new notice of appearance, substituting Alexis Babcock as counsel for Respondent. Notice, ECF No. 30. Chief Special Master Campbell-Smith ordered on August 10, 2011, that Petitioners’ outstanding medical records and a Second Amended Petition, clarifying the legal theory on which Petitioner desired to proceed, would be due by September 9, 2011. Order, ECF No. 31. Petitioners’ counsel failed to file the required documents.

Chief Special Master Campbell-Smith issued an “Order To Show Cause” on September 19, 2011, ordering Petitioners to show cause on or before October 19, 2011, why the case should not be dismissed for failure to prosecute or for failure to establish a compensable vaccine claim. Order, ECF No. 32. On October 19, 2011, Petitioners filed a Response to Chief Special Master Campbell-Smith’s Order to Show Cause. Response, ECF No. 33. Chief Special Master Campbell-Smith then ordered Petitioners to file amended pleadings by October 26, 2011. Order, Non-PDF, Oct. 19, 2011.

On October 25, 2011, Petitioners filed medical records. Filings, ECF Nos. 34-35. Petitioners additionally filed the affidavits of Roxan Winner and William Joe Winner. Filings, ECF Nos. 36, 37. On October 26, 2011, Petitioners filed a Second Amended Petition for Vaccine Compensation, alleging that W.D.W. “sustained an adverse reaction and injury as a result of the initial Hep-B vaccine he received on December 9, 1997 . . . as well as other subsequent vaccines listed herein that he received, especially the DtaP, HIB, and Hep-B vaccines he received on June 10, 1998.” Second Amended Pet. at 4, ECF No. 38. The Second Amended Petition alleged that “with each successive set of vaccines W.D.W. received, he suffered adverse reactions, multiple physical and health problems and injuries such as fever, nausea, pain, irritability, loss of appetite, fatigue, tiredness,

diarrhea, pain, swelling, and redness at the injection site, as well as severe allergic reactions such as rash, hives, difficulty breathing, pain, etc. . . .” *Id.*

On August 6, 2012, Petitioners filed a Third Amended Petition for Vaccine Compensation. Third Amended Pet., ECF No. 58. On September 6, 2012, Petitioners filed a Fourth Amended Original Petition for Vaccine Compensation. Fourth Amended Pet., ECF No. 60.

In the Fourth Amended Petition, Petitioners allege, among other things, that W.D.W. suffered a vaccine injury after receiving a Hepatitis B vaccine on December 9, 1997, and again after administration of DTaP, Hib, and Hepatitis B vaccines on June 10, 1998. Fourth Amended Pet. at 7-8. In the alternative, Petitioners allege aggravation of a pre-existing condition. *Id.* at 8. During a status conference with the parties on September 19, 2012, Chief Special Master Campbell-Smith noted that the challenge for Petitioners would be causally connecting W.D.W.’s alleged injuries to his vaccinations, since Petitioners appear to rely on a mechanism of causation that implicates the thimerosal component in the vaccines. Order at 2, ECF No. 61. The theory of thimerosal-induced harm to a vaccinee’s immune system was carefully considered and rejected in the OAP test cases. *Id.* at 1-2. Chief Special Master Campbell-Smith advised Petitioners’ counsel that any theory presented now must be different from the one advanced in the OAP or must involve previously unconsidered evidence. *Id.* Petitioners’ counsel stated that he was waiting for an opinion letter from Dr. Seshagiri Rao, one of W.D.W.’s treating physicians, to address the issue of causation. *Id.*

From October 19, 2012, through February 15, 2013, Petitioners filed four motions for extensions of time to file an expert report. Motions, ECF Nos. 62, 63, 64, 66.

On March 4, 2013, the case was reassigned to the undersigned. Order, ECF No. 67. On March 15, 2013, Petitioners’ counsel filed a fifth motion for an extension of time to file an expert report. Motion, ECF No. 68. On March 26, 2013, the undersigned held a status conference with the parties to establish a timeline for the filing of Petitioners’ expert report; the undersigned ordered that on or before March 27, 2013, Petitioners’ counsel was to provide medical records to Dr. Rao’s office, and on or before May 2, 2013, Petitioners’ counsel was to file an expert report or a status report, indicating the status of Petitioners’ retention of an expert. Order, ECF No. 69.

Petitioners filed a Status Report on May 2, 2013, indicating that Dr. Rao was unable to file an expert report by the deadline due to illness. Report, ECF No. 70. A status conference was thereafter conducted on May 16, 2013, to discuss the status of Petitioners’ expert report. Order, ECF No. 71. The undersigned informed Petitioners’ counsel that on or before July 18, 2013, Petitioners’ counsel should file an expert report or status report, indicating the status of expert retention. *Id.*

On July 18, 2013, Petitioners filed a status report indicating that they were advised by Dr. Rao's assistant that Dr. Rao would not be providing a report. Report, ECF No. 72. A status conference was conducted on Thursday, July 25, 2013, and again on August 27, 2013, and September 25, 2013, to discuss the status of Petitioners' progress in obtaining an expert report. Order, ECF Nos. 73, 74, 75. During these status conferences, the undersigned ordered that Petitioners' counsel was to file an expert report by noon on September 30, 2013, and that if Petitioners' counsel failed to do so, Respondent's counsel was to file a dispositive motion. *Id.*

Petitioners' counsel failed to file an expert report by September 30, 2013; therefore, Respondent's counsel filed a "Motion To Dismiss For Failure To Prosecute." Motion, ECF No. 76.

## II

### DISCUSSION

To receive compensation under the Program, Petitioners must prove either 1) that W.D.W. suffered a "Table Injury"- i.e., an injury falling within the Vaccine Injury Table- corresponding to one of his vaccinations, or 2) that W.D.W. suffered an injury that was actually caused by a vaccine. *See* §300aa-13(a)(1)(A) and §300aa-11(c)(1).

Petitioners' original petition alleged that W.D.W. suffered from a Table encephalopathy. However, that allegation is not included in the Fourth Amended Petition; the undersigned therefore deems it abandoned. In addition, the medical records do not support the occurrence of a Table encephalopathy. Petitioners must proceed with a theory supporting causation-in-fact.

To establish vaccine causation, Petitioners must satisfy all prongs of the test established by the court in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). To satisfy the first prong of the *Althen* test, Petitioners must provide "a medical theory causally connecting the vaccination and the injury." *Id.* (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir.1992)). Petitioners' theory must show that it is more likely than not that the vaccine(s) W.D.W. received can cause the injuries Petitioners allege the vaccines caused. *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010).

To satisfy the second prong of the *Althen* test, Petitioners must establish "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. That is, Petitioners must show by preponderant evidence (more likely than not) that the vaccine(s) W.D.W. received *did* cause the injuries they allege they caused. *See Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006).

Finally, to satisfy the third prong of *Althen*, Petitioners must produce preponderant evidence of “a proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278. This prong helps to establish the connection between the causal theory of prong one and the more fact-based cause and effect arguments of prong two by demonstrating, “that the onset of symptoms occurred within a timeframe from which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *de Bazan*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

The undersigned is not authorized to make a finding of causation based on the claims of a Petitioner alone, unsubstantiated by medical records or a medical opinion. *See* 42 U.S.C. §300aa-13(a)(1)(B). Although Petitioners sought and received several extensions of time within which to file an expert report, as of September 30, 2013, no report had been filed. A review of the record in this case provides no other evidence demonstrating that W.D.W.’s medical conditions were vaccine-caused. Without such evidence, Petitioners cannot meet their burden of proof under the three-prong test of *Althen*. The undersigned therefore **GRANTS** Respondent’s Motion to Dismiss.

### III

### CONCLUSION

The undersigned is sympathetic to the fact that W.D.W. suffers from numerous medical problems. However, under the law, the undersigned can authorize compensation only if a medical condition or injury either falls within one of the “Table Injury” categories, or is shown by medical records or a competent medical opinion to be vaccine-caused. No such proof exists in this record. **Thus, this case is dismissed for insufficient proof. The Clerk shall enter judgment accordingly.**<sup>7</sup>

**IT IS SO ORDERED.**

/s/ Lisa Hamilton-Fieldman  
Lisa Hamilton-Fieldman  
Special Master

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<sup>7</sup> To preserve whatever right Petitioners may have to file a civil action in another court, they must file an “Election to File a Civil Action” which rejects the judgment from this court within 90 days of the date judgment was filed.