In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: March 19, 2010

MARY BROWNING, mother and next friend of her daughter, MAEVE BRYNILDSON, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	No. 02-0928V TO BE PUBLISHED Entitlement: Thimerosal; Motion for Summary Judgment; Developmental Delay; Althen; Causation

Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA for Petitioner.
Lynn E. Ricciardella, United States Department of Justice, Washington, D.C. for Respondent.

DECISION[1]

I. INTRODUCTION AND SUMMARY

Petitioner Mary Browning filed this case under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. § 300aa-10 et seq., on behalf of her daughter, Maeve Brynildson. Ms. Browning alleges that thimerosal-containing vaccines caused her daughter to suffer from mercury toxicity, leading to a variety of developmental injuries. Despite making a number of efforts, over an extended period of time, to obtain a medical opinion to support her claims, Petitioner has been unable to produce sufficient evidence of causation.

Vaccine Rule 8(d) provides: "The special master may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgment, in which event the procedures set forth in RCFC 56 will apply." Under Rule 56 of the Rules of the United States Court of Federal Claims ("RCFC"), summary judgment is appropriate where there are no genuine issues of material fact and the moving party

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[1] As provided by Vaccine Rule 18(b), each party has fourteen days within which to request the redaction "of any information furnished by that party (1) that is trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Rules of the United States Court of Federal Claims (RCFC), Appendix B, Vaccine Rule 18(b). In the absence of timely objection, the entire document will be made publicly available.

is entitled to judgment as a matter of law.

Summary judgment is appropriate in this case because Petitioner has alleged the existence of factual issues relating to the cause of the vaccinee's developmental delays but has failed to produce medical evidence to support her allegations. A party opposing summary judgment must present evidence showing a genuine issue of material fact; a mere allegation does not create an issue of fact. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Dolney v. Sec'y of Dep't of Health & Human Servs., No. 90-422V, 1990 WL 293865 (Ct. Cl), aff'd, 23 Cl. Ct. 337 (1991), aff'd, 950 F.2d 730 (Fed. Cir. 1991) (awarding summary judgment to the Secretary under the National Vaccine Injury Compensation Program (the "Program")). A finding of entitlement may not be made based on the petitioner's claims alone. § 300aa-13(a)(1). Rather, the petition must be supported by either medical records or by the opinion of a competent physician. See id.; Grant v. Sec'y of Dep't of Health & Human Servs., 956 F.2d 1144, 1148-49 (Fed. Cir. 1992).

In this case, Petitioner was unable to obtain the necessary medical evidence to support her claims. The medical opinion Petitioner submitted was unsupported by scientific data, lacked indicia of reliability, and moreover, did not state that the vaccinee's neurological problems were caused by thimerosal-containing vaccines, as alleged. Without expert medical testimony or other reliable medical or scientific evidence, Petitioner has not made a sufficient evidentiary showing, after seven years, to create a genuine issue of material fact with respect to the elements required to support causation-in-fact. See Althen v. Sec'y of Dep't of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Accordingly, Respondent is entitled to judgment as a matter of law.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Medical History

On October 20, 2003, Petitioner filed an amended petition alleging that "thimerosal-containing vaccines," including diphtheria-tetanus-acellular pertussis ("DTaP"), haemophilus influenzae type b ("Hib"), and hepatitis B, caused Maeve to suffer "mercury toxicity with sequela of seizures, developmental, and other neurological injuries." Amended Pet. at ¶ 1.[2] Maeve and her identical twin sister Katherine ("Kate") were born on February 4, 1999.[3] Id. at ¶ 1. Ms. Browning has alleged that Maeve received her first vaccinations in 1999, and that "[p]rior to receiving the thimerosal-containing vaccines . . . Maeve was a healthy child . . . developing

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[2] Several typographical and other errors in the Amended Petition, as well as in Petitioner's Affidavit, make it difficult to refer accurately to some of the information contained therein.

[3] The factual and legal allegations pertaining to both girls are similar, as are the decisions in their individual cases. See Hopkins v. Sec'y of Dep't of Health & Human Servs., 84 Fed. Cl. 530, 531-32 (2008); Hopkins v. Sec'y of Dep't of Health & Human Servs., 84 Fed. Cl. 517, 519 (2008) (requiring separate opinions).

normally." Id. at ¶¶ 2-3.

In her affidavit, Ms. Browning stated that her twin girls were normal newborns. Petr.'s Ex. 18 at ¶1 [hereinafter "Browning Aff."]. At her six-month checkup, Maeve's pediatrician noted that "Maeve was healthy, with appropriate growth and development." Amended Pet. at ¶ 4. Things changed for the twins on August 8, 1999, when Maeve "had a tonic-clonic seizure six days after the DTaP and Hib shots she received." Browning Aff. at ¶ 5. Maeve suffered from the seizure moments after falling out of her father's arms. Id. at ¶ 5. She was hospitalized and discharged the same day, with a prescription for phenobarbital. Id. In early October, Maeve had a second tonic-clonic seizure "with no apparent trigger." Id. at ¶ 6. After Kate had a tonic-clonic seizure on October 6, 1999, the twins were diagnosed with generalized epilepsy. Id. at ¶ 6. The neurologist did not discuss with Ms. Browning a possible connection with vaccines or thimerosal, and he did not give a specific reason for the seizures. Id. During this time period, Maeve and her sister had normal neurological examinations, appropriate growth and development. Amended Pet. at pp. 5-6.

In June 2000, Ms. Browning "pursued a concern" about Maeve's gait, which, despite "a great deal of physical therapy since then," continued to be abnormal. Id. at ¶ 8 ("still uses an immature step-to pattern to descend stairs"). Despite the gait problem, Ms. Browning has "a clear memory of how normal Maeve was developmentally" in early August 2000, and she "felt the seizures were an inexplicable infancy-thing that was behind us." Id. at ¶ 9. Then, on August 31, 2000, at age 18 months, Maeve received DTaP, Hib, and IPV vaccines. Ms. Browning stated, "[w]hile we felt development was normal up to this time, it was after this set of shots that we realized development nearly ceased." Id. at ¶ 9. After the shots, Ms. Browning began to notice severe language and cognitive deficiencies. Id. at ¶¶ 11-13, 17.

At Maeve's two-year well child visit, on February 6, 2001, her pediatrician noted concerns about speech delay. Id. at ¶ 9. Ms. Browning noticed that both twins failed to interact normally with other people. Id. at ¶ 11. In September 2001, Maeve suffered "what may have been another seizure." Id. at ¶ 15. Maeve's neurologist at the time "had found Maeve and his [sic] sister to have normal development." Id. Nevertheless, "[h]e saw how unresponsive Maeve was in his office, and how she seemed to be in her own world." Id. The doctor recommended further examinations. Id.

In September 2001, Ms. Browning sought a school assessment for both girls. Id. at ¶ 13. The school found that Maeve had a global developmental delay. Id. at ¶ 13. In November 2001, a neuropsychological evaluation showed that Maeve had "a significant global development delay." Amended Pet. at p. 7. The evaluations were "devastating." Browning Aff. at ¶ 17. "These little girls, only 33 months old, who had started out with such perfection and promise, were labeled as having a 'global development delay.'" Id.

Ms. Browning stated that tests performed in August 2002 by Dr. Susan Youngs, a pediatrician specializing in treating autism, were consistent with "heavy metal poisoning." Id. at

¶ 14 (this appears to contradict the report of Dr. Youngs, see Petr.'s Ex. 22 at 4-7, 13-14, discussion, infra). Ms. Browning stated that, in August 2002, Dr. Youngs "assisted us as we have embarked on heavy-metal detoxification." Browning Aff. at ¶ 18. Ms. Browning began treating the twins with an over-the-counter chelating agent. Id. According to Ms. Browning, the girls' lab results were dramatic, showing that their bodies released nickel, tin, cadmium, lead, arsenic, antimony, gadolinium, and uranium, though it is unclear if they released mercury. Id. "Mercury we now know is the hardest thing for the body to release and so comes out last. When we see mercury output we will know we are reaching the conclusion of the process." Id.

Ms. Browning stated that "detoxification" resulted in "amazing progress." Id. at ¶¶ 19-20. According to Ms. Browning, the development of both girls improved significantly after gluten and casein were removed from their diet in 2003, and the use of "a peptide clathrating agent . . . has also been a huge success. The lab work that has been done on Maeve has shown significant levels of heavy metals being emitted from her system." Id. Nevertheless, the twins continued to exhibit speech and cognitive problems. Id. at ¶¶ 21-22. "[I]t's absolutely clear that the children they were when they were born are gone." Id. at ¶ 22.

B. Case Development

A detailed review of the development of these cases shows the propriety of dismissal at this time. The record chronicles the many enlargements of time granted to Petitioner. Despite these numerous accommodations over an extended period, Petitioner still lacks a coherent medical theory and a supporting medical opinion regarding causation.

Petitioner filed her initial petitions on August 2, 2002, without medical records, affidavits, or other documentation. On January 29, 2003, the special master issued an order granting Petitioner authorization to issue subpoenas for Maeve's medical records and requiring Petitioner to file the records received in response "expeditiously." Order, January 29, 2003.

On August 12, 2003, the special master issued an order requiring Petitioner's counsel to "file all available records in the above-captioned case as soon as possible." Order, August 12, 2003. At the request of Petitioner's counsel, the special master stayed the case pending Petitioner's evaluation of the discovery from the autism omnibus proceedings. Id. Petitioner filed medical records on August 19, 2003. On September 12, 2003, the Chief Special Master issued an order transferring the case to another special master and continuing the stay but requiring Petitioner to file medical records for Respondent ("Respondent" or the "Secretary") to review. Order, Sept. 12, 2003.

After reviewing Petitioner's medical records and other filings, Respondent maintained that Petitioner did not satisfy the requirements for compensation under the Vaccine Act. See Respt.'s Supplemental Report, Oct. 20, 2003, at 15-18. On October 20, 2003, Petitioner filed an Amended Petition for Vaccine Compensation. On October 20, 2003, the Secretary filed her supplemental Rule 4(c) report, again stating that the case was not appropriate for compensation.

The case remained stayed for the next three years.

Case activity resumed in early 2006. The Secretary moved the court to require Petitioner to file the medical records of the vaccinee's brother, Colin. According to the Secretary, the medical records documented a family history of seizures and developmental delay and raised the possibility of a genetic cause. See Respt.'s Mot. for Order Requiring Pet'r to File Medical Records of Colin Brynildson, Mar. 9, 2006, at 1-2. Although the motion was never granted, on motion of Petitioner this case subsequently was consolidated with Colin's case.[4]

On September 27, 2006, the special master ordered that, no later than November 9, 2006, "the parties shall file a status report informing the special master about the parties' progress in identifying the amount of thimerosal, if any, in each vaccine that petitioner asserts contributed to Maeve Brynildson's injury." Order, Sept. 27, 2006. The Order required further that the status report "contain a chart identifying coherently each vaccine that [Maeve] received," the date of receipt, the manufacturer and lot number of the vaccine, as well as the source of the thimerosal content of each vaccine. The joint status report was filed on November 9, 2006.

On December 13, 2006, the special master issued an order requiring that Petitioner file a status report by February 23, 2007, informing the special master of the results of Petitioner's "preliminary medical investigation of the case." Order, Dec. 13, 2006.[5] "The special master expects petitioner to represent at a minimum that petitioner has retained a medical expert to review the case and to assist in the development of a medical theory." Id.

On February 23, 2007, Petitioner filed a status report stating she had retained the services

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[4] Petitioner filed a response on April 14, 2006, in which she opposed the motion on the grounds that the relief requested by the Secretary would violate Colin's constitutional right to privacy, among other rights, citing Griswold v. Connecticut, 381 U.S. 479 (1965), and stating that "Colin's genetic predispositions, if any, are not relevant to the petitions of either sister." Id. at 6. Petitioner characterized as "utter nonsense" the Secretary's assertion that Colin's records might shed light on the issue of whether vaccines versus genetic factors caused the problems of all three siblings. Id. at 6.

On June 28, 2007, Ms. Browning filed a petition for compensation under the Vaccine Act on behalf of Colin. No. 07-452V. On May 16, 2008, Petitioner moved to consolidate Colin's claim with those of his sisters, on the ground that the vaccinees in all three cases "allege mercury toxicity as the result of vaccines containing Thimerosal; suffered similar injuries, including speech, language, and attention deficits; have been treated by the same physician; and will likely present the same experts at hearing." The motion to consolidate the cases was granted. Order, June 11, 2008. Colin's case later was terminated voluntarily by Petitioner. See No. 07-453, Petr.'s Mot. For Decision Dismissing His Pet., Oct. 26, 2009. In theory, the dismissal of Colin's case would result in the dismissal of the other consolidated cases. Because the Petitioner's intent was unclear, in this respect, the cases of Maeve and Katherine have been considered individually.

[5] This was more than four years after the original petition was filed.

"of an expert, Dr. Susan L. Youngs, to render opinions in this case and requests 30 days to file an expert report." By Order dated February 27, 2007, the special master set a deadline of April 2, 2007, for the filing of Dr. Youngs's report. Order, February 27, 2007.

On April 2, 2007, Petitioner filed a status report stating that, on March 2, 2007, "counsel for petitioner spoke with Dr. Youngs about a medical expert report in this case. At that time, Dr. Youngs informed counsel that it is her opinion that petitioner has symptoms that place her on the autism spectrum. Accordingly," Petitioner stated, "Petitioner will motion this court to transfer this case into the Omnibus Autism Proceedings." Petr.'s Status Report, Apr. 2, 2007, at 2. Petitioner stated that she would seek the transfer of Maeve's case upon receipt of "all updated medical records that support her position that she now falls within the autism spectrum." Id.

On April 20, 2007, Petitioner requested that the court issue an order for a subpoena to Dr. Youngs, "[d]ue to difficulties obtaining petitioner's medical records." Mot. For Issuance of Subpoena, Apr. 20, 2007; Order, Apr. 23, 2007. The records were obtained on April 26, 2007. Petitioner represented she would file the motion for transfer to the OAP "within 30 days." Petr.'s Status Report, Apr. 30, 2007. On May 1, 2007, the special master issued an order requiring Petitioner to "file all updated records supporting a diagnosis of autism and a motion to transfer the case to the Autism Omnibus Proceeding" no later than June 1, 2007.

On June 1, 2007, "[d]ue to the upcoming Autism Omnibus Hearing," Petitioner moved for a six-week extension of time, until July 20, 2007, to "respond" to the Court Order of May 1, 2007. This motion also was granted. Order, June 11, 2007. Petitioner filed the motion to transfer the case to the OAP on July 20, 2007, stating that Maeve's condition, "[m]ercury poisoning from Thimerosal," is a disorder "similar to autism. Indeed, autism may well be simply a form of mercury poisoning." Petr.'s Mot. To Transfer To Omnibus Autism Proceedings ("Motion To Transfer") at 2.[6]

On April 4, 2008, Special Master John F. Edwards issued an order summarizing the development of the case from the time it was transferred to him in October 2005. Order, Apr. 4, 2008. He noted that he had directed a medical investigation of the case, specifically requiring the retention of an expert and the filing of an expert report. Id. He noted that, instead of filing an expert report on the due date, Petitioner moved to transfer the case to the OAP, notwithstanding

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[6] The Secretary opposed the transfer and asked the special master to "order petitioner to produce evidence to support her request." Resp. and Opp'n To Petr.'s Mot. To Transfer To Omnibus Autism Proceeding, Aug. 3, 2007, at 1. The Secretary asserted that there was no evidence to support the "vague contention" that Maeve's disorder was "similar" to autism. Id. at 5. "Neither petitioner's Motion to Transfer nor the medical records indicates a diagnosis of an autism spectrum disorder." Id. at 6 (citing medical records of Isabelle Beaulieu, Ph.D., who evaluated Maeve on January 26 and 31, 2007). On that basis, the Secretary contended that Maeve did not satisfy the criteria for entry into the OAP. Id. at 7. "The Secretary maintains that the Vaccine Act and Court rules do not permit delaying indefinitely the filing of all necessary records until general "causation" issues are resolved during the OAP. Id. at 5, note 7 (citations omitted).

that Petitioner conceded that Maeve did not have an autism spectrum disorder. Id. The motion to transfer was based on counsel's theory that there was pertinent "'expert testimony and scientific literature'" in the OAP. Id. Special Master Edwards denied the motion to transfer and again ordered Petitioner to file the opinion of her medical expert (on a date more than a year after the previous due date). Id. The special master warned that further enlargements of time were not contemplated, and scheduled an entitlement hearing for November 3, 2008. Id. at 3.

On May 16, 2008, Petitioner submitted a report "on behalf of the Brynildson twins" from Dr. Youngs, a "developmental pediatrician whose practice is concentrated in the care and treatment of special needs patients," including autistic children. Petr.'s Ex. 23 at 1. In the five substantive paragraphs of her medical opinion, Dr. Youngs stated:

> – she first saw the twins in 2002, when both had "speech and language issues." Test results "suggested that neither twin were [sic] 'on the [autism] spectrum.'"
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> – although both twins had been exposed to thimerosal in their routine childhood immunizations, they did not display "the more common signs of mercury toxicity, nor did their blood work reveal frank evidence of mercury toxicity."
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> – after treatment by their mother with an over-the-counter chelating agent, "both twins made remarkable progress. Maeve, the more severely affected twin, demonstrated the greatest gains."
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> – "the Burbacher study in 2005" (no citation to this study was included in the report) indicated that primates exposed to thimerosal retained inorganic mercury. "While the current chelating agents do not generally remove inorganic mercury from the brain, there is some evidence [source unidentified] that it may calm the biochemical processes in the areas of the brain from which autistic symptoms arise. While Maeve and Kate are not autistic, speech and language issues are prominent signs in autistic children."
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> – a "very recent study looked at the speech and language area of the brain in autistic children. This study showed evidence of inflammation, scarring, and replacement of brain tissue with fatty substances which can act as depots for heavy metals. Mercury . . . is a heavy metal."
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> – although "familiar with the current thinking of the biological processes involved in autism, I do not claim to know the changes that occur biochemically, at the molecular level, in these vulnerable children."

Id. at 1-2.

On June 11, 2008, Special Master Edwards ordered that the Secretary file a medical expert's opinion by July 30, 2008, and that, no later than September 12, 2008, each party file a

comprehensive prehearing memorandum, a medical article exhibit list, and a witness list.

On July 17, 2008, the case was reassigned to Special Master Richard Abell. On July 30, 2008, the Secretary filed a motion for summary judgment, described infra.

On April 15, 2009, Petitioner filed the report of Richard C. Deth, Ph.D., a professor of pharmacology, not a physician. Dr. Deth's report stated that "the effects of thimerosal closely parallel the metabolic abnormalities found in autistic children," and that this congruence was convincing evidence that thimerosal causes the major features and symptoms of autism. Petr.'s Ex. 34 at 2. To support this finding, Dr. Deth explored some of the effects that thimerosal and mercury can have on various neurological processes. Id. at 11-15. He concluded that the "molecular actions of thimerosal interfere with brain development and brain function, resulting in the syndrome of autism, as well as other neurodevelopmental impairments." Id. at 16.

On June 17, 2009, Special Master Abell memorialized a status conference in which he stated that Petitioner's "report from a Dr. Deitz" was "generalized and nonspecific" and therefore did not satisfy the Court's previous order. Order, June 17, 2009.[7] Petitioner represented that a new report from Dr. Youngs would be filed. The special master ordered that:

> Petitioner **shall** file, on or before **19 June 2009**, an **expert report** clearly explaining a medical theory causally connecting the vaccination and Maeve's injury, drawing a logical sequence of cause and effect showing that Maeve's vaccination was the reason for her injury, and showing a legally proximate, medically appropriate temporal relationship between the vaccination received and the injury alleged to have been suffered by Maeve in particular.

Id. (emphasis in original). The order stated that the special master would rule on the motion for summary judgment once "that specific, legally sufficient expert report is filed." Id.

On June 19, 2009, Petitioner filed a "Response" to the Court's June 17, 2009 Order. Petitioner explained her failure to comply with the special master's Order on the following grounds:

> In addition to Dr. Youngs' busy clinical practice, she is also engaged in fundraising for a new center on developmental disorders, as well as a new teaching program. Due to Dr. Youngs' extraordinarily busy schedule, she has

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[7] As no report from a Dr. Dietz appears in the record, it appears that this Order refers to the report of Dr. Deth. See Petr.'s Ex. 34. As discussed below, the report of Dr. Deth concerns general effects of mercury on the brain and does not satisfy the requirement that a petitioner "provide a reputable medical or scientific explanation that pertains *specifically* to the petitioner's case . . ." Moberly v. Sec'y of Dep't of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010); see Grant, 956 F.2d at 1148 (medical theory must support the causal link).

advised that she will be unable to submit a report on Maeve's behalf for several months.

Petr.'s Resp. To Ct.'s June 17, 2009 Order at 1. Petitioner stated further that she had contacted "a pediatric neurologist to determine what, if any, availability there is to review Maeve's records and render an expert opinion." Id. at 1-2.

On June 22, 2009, this case was transferred to the undersigned. Following a status conference on June 24, 2009, the undersigned issued an order denying Petitioner additional time for factual development of the cases in response to the Secretary's motion for summary judgment.[8] Order, June 26, 2009. Petitioner was ordered to respond to the motion for summary judgment no later than August 10, 2009. Id. The same order granted Petitioner, over the Secretary's objection, an extra 60 days in which to submit an additional expert report, ordering that such a report be filed no later than August 24, 2009.

On August 24, 2009, Petitioner moved for an extension of time to permit Dr. John Green, "one of Maeve's treating physicians, to supply an expert report on her behalf." Petitioner stated:

> After an initial review of her case, Dr. Green informed petitioner's counsel that he simply did not have the time to adequately address the issues in this case. He advised that his participation in the case would interfere with the care of his other patients.

Petr.'s Mot. For Extension of Time, Aug. 24, 2009. Petitioner noted that she had filed testimony from an expert in the OAP. The Secretary objected to the request for an extension.

The special master denied the motion for 60 more days in which to submit an expert report, citing "growing concerns over the substantial amount of time, over seven years, that has passed since the filing of [these] cases" and noting that Petitioner had been ordered by Special Master Abell to submit an additional expert report more than nine months previously. Order, Sept. 14, 2009.

C. Motion For Summary Judgment and Responses

1. Respondent's Motion For Summary Judgment

In her motion for summary judgment, the Secretary argued that Dr. Youngs's report was

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[8] The order stated that "given the age of these cases and the amount of additional time that already has been afforded petitioner to obtain medical records, no additional time shall be provided for development of the factual record, absent a showing of extraordinary circumstances." Order, June 26, 2009; cf. RCFC 56(e)-(f) (party may be granted additional time to obtain affidavits upon a showing that "for specific reasons, it cannot present facts essential to justify its opposition").

inadequate to establish a "logical sequence of cause and effect" between the vaccination and the twins' injuries. Mot. for Summ. J. ("Motion") at 8-9. The Secretary argued that Dr. Youngs's report did not satisfy the standards in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 591 (1993), in that, under Daubert, expert testimony "must be demonstrably reliable – grounded in good science – to provide an evidentiary basis" for the claim. Motion at 9-10. The Secretary also noted, "[a]t no time does Dr. Youngs ever state that thimerosal-containing vaccines caused or contributed to Maeve's seizure disorder." Id. at 10.

The Secretary explained that she had submitted no responsive expert report because, "[t]here is nothing in Dr. Youngs's report to which an expert for the Secretary can possibly reply because Dr. Youngs never states a theory of causation." Id. at 11. Based on the alleged absence of "any theory of causation," or a "'logical sequence of cause and effect' between vaccination and seizures and/or developmental delay," the Secretary argued that the claim fails "under Federal Circuit precedent and Daubert." Motion at 11-12.

2. Petitioner's Opposition

On August 10, 2009, Petitioner filed her opposition to the motion for summary judgment. Petr.'s Opposition To Mot. For Summ. J., Aug. 10, 2009 ("Opp."). Petitioner briefly described Maeve's history of tonic clonic seizures. Following an evaluation by a pediatric neurologist, the impression was "generalized epilepsy of perhaps a genetic basis." Opp. at 2. "At eighteen months, her growth and development were still considered appropriate," however Maeve still had no clear speech at age two, and she was evaluated as having significant global development delay. Id. at 2-3.

Petitioner stated that Maeve received 11 vaccines containing thimerosal "before her diagnosis of developmental delay." Id. at 3. According to the Opposition, Maeve was subsequently evaluated by Dr. Youngs, who "described Maeve's developmental growth as normal until she received heavy exposure to mercury-containing vaccines." Id. at 4. Dr. Youngs was willing "to follow Maeve while her mother administered an over-the-counter chelating agent." Id.

Petitioner cited the testimony of Dr. George Lucier, "a toxicologist who testified for the petitioner in Kolakowski v. Secretary of HHS, the representative case in the thimerosal omnibus proceeding." Id. at 4; see Petr.'s Ex. 36, Kolakowski Tr. 1-257, June 9, 2008.[9] After several pages describing Dr. Lucier's qualifications and career, Petitioner summarized Dr. Lucier's testimony in the Kolakowski proceeding regarding the toxic effects of thimerosal. Opp. at 4-15. Noting that, "[t]himerosal contains almost 50% ethyl mercury," Petitioner expatiated on the adverse effects on human health of methyl mercury. Id. at 7-10. Petitioner's wide-ranging

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[9] Kolakowski v. Sec'y of Dep't of Health & Human Servs., No. 99-625, is the test case in the thimerosal omnibus proceeding, which is a group of 25 pediatric death cases where thimerosal allegedly caused the death. The test case has been heard but the proceedings are still *sub judice*.

treatment of the topic noted the many sources of mercury, mercury contamination in Japan, mercury poisonings in Iraq, acceptable levels of mercury under EPA, CDC, and FDA standards, the findings of the "Clinton White House Science group," the findings of investigators from the Seychelles and Faroe Islands, and a study by the National Academy of Sciences on "Toxicological Effects of Methylmercury." Id. at 8-10.

Petitioner maintained that Dr. Lucier's testimony shows that since "methyl mercury and ethyl mercury differ only by the extra methyl group (carbon molecule) in methyl mercury, it was acceptable practice to extrapolate the methyl mercury data to ethyl mercury." Id. at 11.[10] The Opposition then extensively discussed certain "clearance studies" involving ethyl mercury. Id. at 12-15. Petitioner conceded that one of the articles discussed was "inadequate" to address the issue of ethyl mercury's effects on neurological development. Id. at 13 ("[s]ince the concerns about thimerosal are not blood toxicity, but brain toxicity, the Pichichero article is inadequate to address the issue of neurotoxicity"). The discussion concluded with the statement that "a prolonged latency period between mercury exposure and the onset of neurological injury is acknowledged and supported by the medical literature." Id. at 15.

The Opposition next addressed the report by Dr. Deth, who reported that "parents of autistic children demonstrate a genetic vulnerability for the deleterious type of biochemical reactions caused by chemicals such as thimerosal." Id. at 15-16. "If this vulnerability is passed onto their children, their exposure to the thimerosal contained in the early childhood vaccines they receive may trigger their autism." Id. Dr. Deth cited research indicating a link between autism and genetic factors. Id. Over the next seven pages, the Opposition described the technical theories supporting Dr. Deth's opinion that thimerosal can cause autism. Id. at 16-23.

Turning back to Dr. Youngs, the Opposition discussed Dr. Youngs's "brief report," dated May 3, 2008, which stated that Maeve had "speech and language issues" when first evaluated but was not "on the [autism] spectrum." Id. at 23. Dr. Youngs also noted that "Maeve did not have the common signs associated with mercury toxicity nor did her blood work reveal frank evidence of mercury toxicity." Id. When treated with over-the-counter chelation agents, "Maeve improved considerably." Id. Dr. Youngs "noted that recent literature supported the fact that chelation 'may calm the biochemical processes in the brain from which autistic symptoms arise.'" Id. The Opposition noted that while Maeve was "not autistic, speech and language issues are prominent in autistic children." Id. Petitioner then discussed the "Lopez-Hurtado study," to show "that outside the formal diagnosis of autism, there exists an unexpectedly large population with milder, but significant, social and communication deficits." Id. at 24-25.

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[10] The Opposition did not mention the second article referenced by Dr. Youngs in her report. See id. at 28, Pet. Ex. 23. That article, entitled "Comparison of Blood and Brain mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccines Containing Thimerosal," by Burbacher, et al., 113 Environmental Health Perspectives 1015, concluded that "[t]he results indicate that MeHg [methylmercury] is not a suitable reference for risk assessment from exposure to thimerosal-derived Hg [mercury]."

Finally, the Opposition argued that, construing the evidence in the light most favorable to Petitioner, the motion for summary judgment should be denied. "Logically, if heavy metals can cause oxidative stress and neuronal death in autistic children, it can also cause a lesser degree of damage for that unexpectedly large population that suffers milder forms of the communication and social deficits observed, like that experienced by Maeve." Id. at 29.

3. The Secretary's Reply

On August 24, 2009, the Secretary filed her Response to Petitioner's Opposition To The Motion For Summary Judgment ("Reply"), renewing her motion "to enter judgment in favor of the Secretary and to dismiss the petition." Reply at 1. The Secretary again asserted that the report from Petitioner's medical expert, Dr. Youngs, was legally insufficient to sustain Petitioner's burden of proof. Id. "Dr. Youngs offered no medical or scientific theory whatsoever as to how Maeve's receipt of thimerosal-containing vaccines caused her alleged injuries." Id. "In fact, Dr. Youngs never opines that thimerosal-containing vaccines caused Maeve's alleged injuries at all." Id. at 1-2 The Reply noted that Dr. Youngs's report refuted any suggestion that Kate suffered from "mercury toxicity," at least as of Dr. Youngs's initial examination. Id. at 2. The Reply dismissed the assertion that the twins made "remarkable progress" after treatment with an over-the-counter chelation agent as "mere conjecture" and not proof of a "'logical sequence of cause and effect' showing that thimerosal-containing vaccines caused Maeve's condition." Id.

The Reply asserted that Dr. Youngs's reference to the Burbacher study "never offers any explanation as to how this study relates to Maeve," and alleged the same flaw with respect to the article by Lopez-Hurtado, noting that "counsel's interpretation of the article does not overcome the patent insufficiency of Dr. Youngs's expert report." Id. at 2-3. The Secretary noted that Dr. Youngs's report did not actually cite to the Lopez-Hurtado study itself, and stated that the study had no bearing on Maeve's case because (1) Maeve did not have autism and (2) there was no evidence that the subjects in the article ever were exposed to thimerosal. Id. at 3. The Secretary laid emphasis on the lack of an opinion in the report explicitly linking thimerosal-containing vaccines with Maeve's developmental delay. Id.

The Reply cited and quoted the Order, issued on January 26, 2009, directing Petitioner to file a "legally sufficient expert report" addressing "a theory of causation specific to Maeve's alleged vaccine injury." Id. This was followed, according to the Reply, by three additional court orders "explicitly" directing Petitioner to file such a report. Id. at 4. In response, Petitioner filed, on April 15, 2009, the report of Dr. Deth. The Secretary contended that Dr. Deth's report was not compliant with the referenced orders because (1) his report addressed autism, which Maeve did not have; and (2) his report made no mention of Maeve, and thus did not provide a "'logical sequence of cause and effect' showing how Maeve's vaccinations caused her condition." Id. The Reply cited the special master's order noting that Dr. Deth's report was "'generalized and nonspecific, i.e., not what was ordered previously by the Court.'" Id. (citing and quoting Order,

June 17, 2009).

The Secretary asserted that Dr. Lucier's report, first filed with Petitioner's Opposition, "suffers from the same fatal flaw." Reply at 4. As noted by the Secretary, Dr. Lucier's report was filed by claimants in an unrelated case pending before a different special master, in which the petitioners alleged a death resulting from thimerosal-containing vaccines. Id. at 5. "Dr. Lucier's report is another generalized and non-specific report that does not comply with the Court's Orders, and does not satisfy petitioner's burden of proof." Id. at 5. The Secretary noted that Dr. Lucier's report makes no mention of Maeve and "never draws a causal connection between Maeve's receipt of thimerosal-containing vaccines and her developmental delay." Id.

The Secretary appeared to concede that "arguably," through the generalized expert reports of Drs. Deth and Lucier, Petitioner had offered a medical theory as to how thimerosal-containing vaccines could cause developmental delay. Nevertheless, the Secretary argued, even assuming that the theory presented were reliable, neither doctor offered "any medical opinion as to how thimerosal-containing vaccines caused Maeve's condition." Id. In addition, the Secretary noted that neither Dr. Deth nor Dr. Lucier would be qualified to offer a medical opinion because neither is a medical doctor. Id. As a result, the Secretary maintained, Petitioner was compelled to rely exclusively on Dr. Youngs to establish a logical sequence of cause and effect linking Maeve's condition to her vaccination. Id. at 5-6.

The Secretary asserted that "the full extent" of the medical evidence upon which Dr. Youngs relied was that Maeve "'had been exposed to the mercury containing preservative thimerosal in her routine childhood immunizations'" and "'subsequent to chelation, she made remarkable progress.'" Id. at 6. According to the Secretary, Dr. Youngs's opinion "falls far short of presenting a coherent and logical sequence of cause and effect." Id. The Secretary asserted further that Petitioner "offered no evidence at all showing a medically appropriate temporal relationship between Maeve's thimerosal-containing vaccines and the onset of her condition." Id.

Based on these deficiencies, the Secretary asserted that Petitioner had not and could not sustain the burden of proving a vaccine injury. Id.

III. DISCUSSION

A. The Standards For Summary Judgment

Vaccine Rule 8 instructs the special master to use the procedures set forth in RCFC 56 in evaluating a motion for summary judgment. RCFC 56(c) provides:

> (1) *In General.* A motion for summary judgment should be granted if the pleadings, the discovery and disclosure materials on file, and any affidavits show

> that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.

Further, RCFC 56(e)(2) provides that:

> When a motion for summary judgment is properly made and supported, an opposing party may not rely merely on allegations or denials in its own pleading; rather, its response must – by affidavits or as otherwise provided in this rule – set out specific facts showing a genuine issue for trial.[11]

See Crown Operations International, Ltd. v. Solutia Inc., 289 F.3d 1367, 1375 (Fed. Cir. 2002) (reviewing applicable precedent for summary judgment under FRCP 56(c) in a patent case); Jay v. Sec'y of Dep't of Health & Human Servs., 998 F.2d 979, 982-83 (Fed. Cir. 1992) (interpreting Vaccine Rule 8(d) to authorize summary judgment and stating that summary judgment in vaccine cases should be treated the same as in other cases). "When ruling on summary judgment . . . 'the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.'" Jay, 998 F.2d at 982 (quoting Anderson, 477 U.S. at 249). The party opposing summary judgment, however, has the burden of demonstrating the existence of a genuine issue of material fact, in other words, that there is evidence sufficient "to permit a reasonable factfinder to find in favor of the nonmoving party." Jay, 998 F.2d at 982-83. However, a special master may not make factual findings in ruling on a motion for summary judgment. Id.

As discussed below, even assuming that all of the factual allegations and the inferences reasonably to be drawn from the facts are true as stated by Petitioner, the record does not establish causation-in-fact under the requirements of Althen v. Secretary of Department of Health and Human Services, 418 F.3d 1274. To prevail in a case under the Vaccine Act, petitioners must provide evidence, in the form of medical records or reliable medical opinion, to establish that (1) the vaccine(s) in question can cause the type of injury suffered by petitioner; (2) the vaccine(s) in question did cause the petitioner's injury; and (3) the time of onset of the petitioner's injury is consistent with vaccine injury. Althen, 418 F.3d at 1278. Petitioner here has not submitted sufficient evidence under any of the Althen criteria. As a result, she cannot prevail, as a matter of law. Under such circumstances, summary judgment is an appropriate device for terminating litigation. "One of the principal purposes of the summary judgment rule is to isolate and dispose of factually unsupported claims or defenses." Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986). See Anderson, 477 U.S. at 249-50 (stating that "there is no issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party").

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[11] Affidavits are not required in the more informal setting of a Vaccine Act case. A showing of specific facts demonstrating a genuine issue requiring resolution is required, however. Mere legal argument and/or bare speculation is not sufficient. See discussion, infra.

B. Absence of Legally Supportable Causation

1. Applicable Standards Under The Vaccine Act

The Vaccine Act created the National Vaccine Injury Compensation Program ("Vaccine Program") under which compensation may be paid for vaccine-related injury or death. 42 U.S.C. § 300aa-10(a); Walther v. Sec'y of Dep't of Health & Human Servs., 485 F.3d 1146, 1149 (Fed. Cir. 2007). To establish entitlement under the Vaccine Program, petitioners must demonstrate by a preponderance of the evidence that, among other matters, they received a vaccine in the United States or its trust territories, and sustained or had significantly aggravated an illness, disability, injury or condition resulting from the vaccine. See 42 U.S.C. § 300aa-11(c).

A petitioner can establish causation in two ways. Under the Vaccine Injury Table (the "Table"), a petitioner who shows that he received a vaccination listed in the Table and suffered an injury listed in the Table within the time period specified gains a presumption of causation. Walther, 485 F.3d at 1149 (citing 42 U.S.C. § 300aa-11(c)(1)(C)(i)); Pafford v. Sec'y of Dep't of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). Under the second method, a vaccinee who did not suffer an injury listed in the Table, or did not suffer the injury within the time frame specified, can establish entitlement by proving "causation-in-fact," De Bazan v. Sec'y of Dep't of Health & Human Servs., 539 F.3d 1347, 1351 (Fed Cir. 2008), meaning that the injury was actually caused by the vaccine, Walther, 485 F.3d at 1149.

Petitioner here did not claim entitlement under the Vaccine Injury Table and therefore must prove actual causation. "Proof of actual causation "'must be supported by a sound and reliable medical or scientific explanation that pertains *specifically* to the petitioner's case . . .'" Moberly v. Sec'y of Dep't of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (citing Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)) (emphasis added); see also Grant, 956 F.2d at 1148 (medical theory must support the causal link).

2. Application of the Althen Factors

a. Prong 1 – Petitioner Presented No Reliable Theory of Causation

To establish prong (1), a petitioner must set forth a biologically plausible theory explaining how the vaccines received by the petitioner could cause the injuries complained of. See, e.g., Andreu, 569 F.3d 1367, 1375 (Fed. Cir. 2009); Pafford, 451 F.3d at 1355-56 (approving special master's prong (1) inquiry: "can the vaccine(s) at issue cause the type of injury alleged?"). In this instance, Petitioner suggested a theory that the thimerosal in various vaccines can cause speech and developmental delay and other neurological injuries. Petitioner asserted, "if heavy metal exposure can cause oxidative stress and neuronal death in autistic children, it can also cause a lesser degree of damage in a larger population that suffers milder forms of communication and social deficits, like those experienced by Maeve." Opp. at 29.

Petitioner cannot satisfy Althen prong (1) because Petitioner has not placed into evidence an expert's report endorsing the theory that thimerosal in vaccines can cause speech and language disorders. Although, to prove causation, it is unnecessary to present medical literature or epidemiological studies linking the vaccine to the injury, or to show general acceptance in the medical community, a petitioner must present evidence sufficient to establish a plausible theory of causation. Moberly, 592 F.3d at 1324. Without an expert's report opining that thimerosal-containing vaccines can cause speech and language delays, that fundamental requirement has not been met here.

First, the report of Dr. Deth opined on a possible relationship between thimerosal and autism and described how mercury affects brain development. Assuming that his report was scientifically valid, it was insufficient to support a finding that thimerosal can cause the type of injuries suffered by Maeve. Dr. Deth's report addressed thimerosal and autism, but the vaccinee, according to her own expert and treating physician, Dr. Youngs, did not have autism. Although Dr. Deth's report is entitled "How Thimerosal Causes Neurodevelopmental Disorders and Autism," the report opined on no causative link between thimerosal-containing vaccines and speech and language disorders, or seizures.[12] That causative connection was made only by Petitioner, based on a layman's argument that various developmental disorders are "lesser included" features of autism. See Opp. at 29. Petitioner's unsupported allegations do not create a genuine issue for trial on the requirement to show a plausible theory of vaccine causation under prong (1) of Althen.

Second, the report of Dr. Lucier opined on the toxicity of ethyl mercury by extrapolating from methyl mercury data, and theorized that the thimerosal in vaccines can cause death. The vaccinee here did not suffer death. Nor did her treating physician find signs of heavy metal poisoning. Petr.'s Ex. 22; Petr.'s Ex 23. Thus, nothing in Dr. Lucier's testimony established a link between thimerosal and the vaccinee's developmental disorders or seizures.

Third, the report of Dr. Youngs did not set forth a biological theory that thimerosal in vaccines can cause disorders like those suffered by the vaccinee. Dr. Youngs did not even purport to present such a theory.

> While I make a diligent effort to keep current with new literature and am familiar with the current thinking of the biological processes involved in autism, I do not claim to know the changes that occur biochemically, at the molecular level, in these vulnerable children.

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[12] The Deth report at various points mentioned "autism and related neurodevelopmental problems (injuries, issues)" but did not identify speech and language delays or seizures as among the "problems, injuries or issues." See e.g., Petr.'s Ex. 34 at 3. In passing, the Deth report mentioned (one mention for each named disorder) "developmental disorders, including Rett, Angelman's, Prader-Willi and Fragile-X syndromes" see id. at 9-10, and ADHD, see id. at 15. None of these conditions is among Maeve's diagnoses.

Petr.'s Ex. 23 at 2. Dr. Youngs's report provided no explanation of possible causation that is either sound, reliable, or scientific. She merely offered the observation that Maeve and her sister were "vulnerable" children, with no indication of how they were vulnerable, or in what way their vulnerability resulted in disorders caused by thimerosal-containing vaccines.[13]

Fourth, the Lopez-Hurtado study demonstrated changes in the speech and language areas of autistic brains. Again, according to their treating physician and expert, Dr. Youngs, the twins' developmental problems did not place them on the autism spectrum. Petr.'s Ex. 22. Moreover, there was no evidence that the subjects in the Lopez-Hurtado study ever were exposed to thimerosal.

Fifth, the Burbacher study concerned retention of inorganic mercury by monkeys exposed to thimerosal. According to Dr. Youngs, who mentioned the study but did not explain its relevance, if any, to Maeve's case, see Petr.'s Ex. 23 at 2, there was no medical evidence that Maeve suffered from mercury toxicity. Indeed, Ms. Brynildson's Affidavit indicated that Maeve did not excrete mercury in response to chelation, which supposedly resulted in marked improvement in Maeve's condition. Browning Aff. at ¶¶ 18-20. This undercut Petitioner's contention that retained inorganic mercury somehow caused Maeve's disorders, and further diminished the relevance of the Burbacher study.

It follows from the above deficiencies, and others discussed infra, that Petitioner has not presented probative evidence that thimerosal in vaccines can cause the type of disorders suffered by Maeve. This is fatal to Petitioner's case. See Moberly, 592 F.3d at 1322; cf. Andreu, 569 F.3d at 1375 (first prong satisfied because petitioners' medical expert "presented a 'biologically plausible theory establishing that toxins in the whole-cell pertussis vaccine can cause seizures"). In contrast to Andreu v. Secretary of Department of Health and Human Services, where the testimony of an expert with "'excellent medical credentials'" testified in support of prong (1), see 569 F.3d at 1377 n. 4, in this case no qualified expert has testified that there is a possible link between thimerosal and developmental delays or seizures; nor is there any medical literature setting forth such a link, much less establishing a scientific basis for it.

Recognizing the difficulties in proving causation in a field "bereft of complete and direct proof of how vaccines affect the human body," the Vaccine Act affords petitioners wide latitude in the type of evidence that may be used to show causation. Andreu, 569 F.3d at 1379 (citing and quoting Althen, 418 F.3d at 1280). Accordingly, a petitioner can satisfy prong (1) by showing evidence in the form of reliable medical opinion, medical literature, or epidemiological studies. The requirement, as Althen makes clear, is "that a claimant's theory of causation must be supported by a 'reputable medical or scientific explanation.'" Andreu, 569 F.3d at 1379; see also Knudsen, 35 F.3d at 548. In this case, Petitioner has failed to present reliable medical opinion,

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[13] Of course, understanding "at the molecular level" is not required by Althen. The point here is that Dr. Youngs' presented no coherent theory explaining possible causation of how the vaccines could have caused the type of injury suffered by Maeve.

literature, epidemiological studies, or other scientific evidence that thimerosal can cause the type of injuries suffered by Maeve. Therefore, as a matter of law Petitioner has not satisfied prong (1) of Althen.

b. Prong Two – No Logical Sequence of Cause and Effect

The second prong of Althen requires Petitioner to prove that "'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Andreu, 569 F.3d at 1374 (citing and quoting Althen). Petitioner's allegations that Maeve was developing normally until she received thimerosal-containing vaccines do not suffice to carry the burden of establishing causation under prong (2). Petitioner has produced no medical records in which a physician or other health professional identified vaccines as the cause of Maeve's developmental problems.[14]

In an appropriate case — for example, where petitioners produce evidence sufficient to meet the requirements of prong (1) and prong (3) of the Althen test — a court may rely solely on the testimony of a treating physician to establish prong (2). See Moberly, 592 F.3d at 1324-25 (discussing Andreu, in which, in addition to satisfaction of prongs (1) and (3), "there was direct testimony from treating physicians stating 'unequivocally' that the DPT inoculation caused [the petitioner's] seizures"). As discussed herein, in this case, Petitioner cannot meet the requirements of prong (1) or (3). However, even assuming that Petitioner could satisfy those prongs, Dr. Youngs's report fails to satisfy prong (2).

The most salient point about Dr. Youngs's report is that, in actuality, she expressed no opinion as to causation. She simply stated facts, reporting on the history of her professional experience with the twins. Having determined by testing that they did not suffer from an autism spectrum disorder or mercury toxicity, she reported no further medical treatment. Instead, the children were administered an over-the-counter chelating agent by their mother, and subsequently made "remarkable progress." Petr.'s Ex. 23 at 1.[15] Notably absent from this account was any confirmation by Dr. Youngs of the attenuated chain of causation Petitioner seeks to establish: that the twins received vaccines containing thimerosal, that the thimerosal in the vaccines caused mercury toxicity, that the chelating agent removed the mercury, and that the twins improved as a result. To the contrary, Dr. Youngs's testimony that the girls "did not display the more common signs of mercury toxicity, nor did their blood work reveal frank evidence of mercury toxicity," tended to undermine the Petitioner's theory. Id.; see Moberly, 592 F.3d at 1323-24 (upholding

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[14] The physician who performed genetic testing on the twins responded to a question from Ms. Browning regarding the relationship between vaccines and the twins' medical condition. On May 21, 2002, Dr. David Aughton noted that although the question was really "beyond the scope of a clinical genetics evaluation," he "consider[ed] it unlikely that Kate's and Maeve's neurological difficulties were *caused* by the immunizations that they received . . ." Petr.'s Ex. 7 at 17 (emphasis in original).

[15] Again, the girls' mother's purely anecdotal report of "amazing progress" due to heavy-metal detoxification, see Browning Aff. at ¶ 19, is not sufficient to establish causation, see 42 U.S.C. § 300a-13(a)(1).

special master's finding that treating physician discussed the vaccine and injury but never found vaccine was cause).

The final paragraphs of Dr. Youngs's report related only obliquely to Petitioner's theory of causation, as Dr. Youngs never stated that the thimerosal containing vaccines caused Maeve's disorders. Instead, she provided a series of loosely connected musings related to two studies, neither of which was fully identified in her report. She referred to the "Burbacher study in 2005" indicating that "primates exposed to thimerosal retained more inorganic mercury from ethyl mercury than those who ingested methylmercury laden food." Petr.'s Ex. 23 at 2. "It is my understanding," she continued, that "inorganic mercury takes a very long time to leave the brain." Petr.'s Ex. 23 at 2. What these observations meant for Maeve's case was unstated. Further, Dr. Youngs did not reveal the source of her "understanding." Without knowing the scientific basis for Dr. Youngs's statement, the court cannot rely on it.[16]

The remainder of Dr. Youngs's report discussed mercury in the context of autistic children. Dr. Youngs's comments concerning "the calming effects" of chelation on the brains of autistic children were devoid of scientific or medical information and irrelevant to the vaccinees, who are not autistic. In recognition of this deficiency, Dr. Youngs added that, "while Maeve and Kate are not autistic, speech and language issues are prominent signs in autistic children." No conclusion, however, was stated by Dr. Youngs based on this observation. It would be illogical, in any event, to conclude that, because autistic children share symptoms with non-autistic children, the cause of the symptoms necessarily is the same.

Dr. Youngs also referred to "[a] very recent study" (unidentified in her report), showing evidence of brain tissue damage in "the speech and language areas of the brain in autistic children." Id.[17] In autistic children, Dr. Youngs reported, "[t]his study showed . . . replacement of brain tissue with fatty substances which can act as depots for heavy metals. Mercury, as the court is probably aware, is a heavy metal." Id. Again, Dr. Youngs did not state that the results of the study referred to would be applicable to children with neurological problems who are not autistic. In the absence of a reliable medical opinion making that connection, the study cannot be applied to Maeve. To do so, in the absence of any evidence, much less reliable evidence, would

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[16] As a general matter, before a court may consider scientific evidence, its proponent must establish that the evidence has "a valid scientific connection to the pertinent inquiry" before the court. Daubert, 509 U.S. at 591-92. Where the "factual basis, data, principles, methods, or . . . application" of expert opinion is called into question, "the trial judge must determine whether the [expert's opinion] has a reliable basis in the knowledge and experience of the relevant discipline." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 149 (1999) (quotations omitted); see Terran v. Sec'y of Dep't of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (sanctioning use of Daubert in vaccine cases "as a tool or framework for conducting the inquiry into the reliability of evidence").

[17] This reference apparently is to the Lopez-Hurtado study filed with Dr. Youngs' report as Exhibit 23 Tab B. The "Burbacher study" referred to by Dr. Youngs was submitted with her report as Exhibit 23 Tab A.

be pure speculation, which Dr. Youngs evidently was unwilling to engage in. Her report omitted precisely what needed to be proven: a logical sequence of cause and effect between the vaccines and Maeve's impairment.

c. Prong Three – No Temporal Relationship Between Vaccine and Injury

Petitioner presented no evidence showing "a proximate temporal relationship between vaccination and injury." Moberly, 592 F.3d at 1322 (citing and quoting Althen). Dr. Youngs's report certainly contained no opinion or information illuminating the issue of why the amounts of thimerosal received by the girls allegedly produced their developmental disorders when they did, much less, whether that time frame is appropriate to ascribe causation to the vaccinations.

The absence of a time frame specifically linking thimerosal to the onset of Maeve's disorder reflects the vagueness and generality of Petitioner's allegations. Petitioner merely stated, "[d]uring her infancy and early childhood, before her diagnosis of developmental delay, Maeve received the following thimerosal-containing vaccines." Opp. at 3. Petitioner produced no evidence showing which thimerosal dose or doses allegedly caused Maeve's condition, or indicating how the appearance of certain symptoms corresponded to the timing of her vaccinations. Petitioner made no effort to present any evidence, scientific or otherwise, concerning a presumed dose response between thimerosal and developmental delay.

Petitioner asserted, without benefit of any supporting data, that Maeve's development was "normal until she received heavy exposure to mercury-containing vaccines." Opp. at 4. The record does not indicate what constitutes "heavy" exposure. Petitioner asserted that Maeve failed to develop normally only "after" receiving the allegedly "heavy" exposure. Id. The record does not indicate "how long after." As a result, there is no factual basis on which to make the finding required by Althen concerning timing. All that is known is, in the two-year period following her birth, Maeve received 11 vaccinations allegedly containing various amounts of thimerosal. It cannot be determined, from the information presented by Petitioner, at what point during that two-year-period the thimerosal-containing vaccinations allegedly caused Maeve's developmental problems. Causation-in-fact cannot be established absent such information. Cf. Hennessey v. Sec'y of Dep't of Health & Human Servs., No. 01-190VC, 2010 WL 94560 (Fed. Cl. Jan. 7, 2010) , at *15 (expert's "proposed timing suffers from the same overly broad scope as his proposed medical theory . . . . In effect [the expert's] testimony renders Althen's third prong a nullity").

IV. CONCLUSION

Accepting all the Petitioner's factual allegations and the reasonable inferences to be drawn therefrom as true, this record does not permit a finding in favor of Petitioner. The large gaps between the evidence submitted and the injuries suffered by the vaccinee preclude such a finding. No material factual dispute appears in the record, only an absence of proper evidence

necessary to establish vaccine injury causation. It is manifest that on this record, no reasonable factfinder could find for Petitioner.

Accordingly, Respondent's Motion For Summary Judgment is GRANTED and the Petition is DISMISSED. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

s/ Dee Lord
Dee Lord
Special Master