In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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FORREST Q. SPAHN,	*	No. 09-386V
	*	Special Master Christian J. Moran
Petitioner,	*	
	*	Filed: September 11, 2014
v.	*	Reissued: July 31, 2017
	*	Entitlement; tetanus-diphtheria ("Td")
SECRETARY OF HEALTH	*	vaccine; significant aggravation
AND HUMAN SERVICES,	*	of obsessive-compulsive disorder
	*	("OCD"); tics; summary judgment;
Respondent.	*	dose-response relationship.
* *		

Paul Dannenberg, Huntington, VT, for petitioner;
Voris E. Johnson, Jr., United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION GRANTING MOTION FOR SUMMARY JUDGMENT[1]

By age 15, Mr. Spahn was suffering from obsessive-compulsive disorder ("OCD"). He then received a dose of the tetanus-diphtheria ("Td") vaccine. Mr. Spahn claims that the vaccination caused a significant aggravation of his pre-existing OCD. Specifically, Mr. Spahn claims that he first developed tics after this vaccination. Mr. Spahn seeks compensation for the worsening of his OCD through the National Childhood Vaccine Injury Compensation Program, which is codified at 42 U.S.C. § 300aa—10 through 34 (2006).

[1] After the decision was issued to the parties, Mr. Spahn filed a timely motion to redact pursuant to Vaccine Rule 18(b). This motion was granted in part. Order, filed October 29, 2014. Mr. Spahn filed a motion for review of the partial denial of the motion for redaction. On July 27, 2017, the Court denied the motion for review. Thus, the decision is now available to the public.

Mr. Spahn has filed reports from two people, Burk Jubelt (a neurologist) and H. Vasken Aposhian (a toxicologist). The Secretary contested the opinions in those reports by presenting reports from Michael Kohrman (a pediatric neurologist) and Jeffrey Johnson (a toxicologist).

In anticipation of testimony from these four witnesses, a hearing was scheduled for November 14-15, 2013. The Secretary, however, filed the pending motion for summary judgment on July 23, 2013, arguing that she is entitled to judgment and the hearing is not necessary. The Secretary essentially contends that the opinions of Dr. Jubelt and Dr. Aposhian are not sufficient for Mr. Spahn to prevail because their opinions are unreliable due to the gaps within them.

Despite many opportunities to add to the record, Mr. Spahn did not fill these gaps. His response to the motion for summary judgment did not show any need for a hearing to resolve a genuine dispute about a material fact. Consequently, the Secretary's motion for summary judgment is GRANTED. The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.

I. Medical History[2]

Mr. Spahn was born in [redacted] 1991. Exhibit 3 at 32. Before his birth, his mother's pregnancy was complicated. Her membranes spontaneously ruptured at 26 weeks gestation, she had premature labor occasionally, and she was prescribed RhoGam at 28 weeks. Mr. Spahn's mother also developed

[2] Mr. Spahn's medical history is not contested. After he was directed to present a comprehensive recitation of relevant facts, order, filed July 2, 2013 at 3-4, Mr. Spahn responded that the Secretary "has described [his] medical history fairly comprehensively in her Rule 4 Report and in her motion for summary judgment." Pet'r's Prehear'g Br., filed Sept. 30, 2013, at 6.

leukocytosis[3] and a fever. As a consequence, her doctor recommended delivery by caesarian section, which occurred at 33 weeks gestation. Id. at 32-36.

When Mr. Spahn was born, his weight was 1,860 grams (slightly more than four pounds), his length was 40.5 centimeters (approximately 16 inches), and his head circumference was 31 centimeters (approximately 12 inches). His Apgar scores were four, eight and eight at one minute, five minutes, and ten minutes. Among other problems at birth, Mr. Spahn had respiratory distress and received oxygen in the delivery room. Exhibit 3 at 31, 36. He was transferred to the neonatal intensive care unit where he remained for four days. Id. at 31.

On his fourth day of life, Mr. Spahn was transferred to a different hospital, Alexian Brothers Medical Center. He remained there for approximately one month. Exhibit 4 at 16.

Medical records from his early life are relatively sparse. A note from a medical appointment when he was 9 years old states that vaccinations had been deferred. Exhibit 4 at 21. Mr. Spahn's mother claimed a religious exemption from vaccination. Exhibit 5 at 3-4 (undated), 6 (dated Dec. 30, 2006).

According to a report given in April 2008, Mr. Spahn acted in ways consistent with attention deficit disorder when in elementary school. He also was not a very social child. Exhibit 12 at 11. The lack of records created during this time makes confirming (or rejecting) this history difficult. A small measure of support comes from a report in which his mother reported that Mr. Spahn had tics.[4] Exhibit 5 at 8. Regardless, the parties appear to accept that Mr. Spahn suffered

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[3] Leukocytosis is "a transient increase in the number of leukocytes in the blood; seen normally with strenuous exercise and pathologically accompanying hemorrhage, fever, infection, or inflammation." Dorland's Illustrated Medical Dictionary 1028 (32nd ed. 2012).

[4] The context of this report suggests that it was made in 2004, when Mr. Spahn was 13. If this report is accurate, then Mr. Spahn's tics existed before vaccination. An onset before vaccination would further complicate Mr. Spahn's attempt to establish that his OCD was worse after vaccination. Despite the notation in the medical record that Mr. Spahn was having tics, the parties have not discussed the onset of tics. Therefore, for purposes of deciding the motion for summary judgment, it is assumed that Mr. Spahn's tics started after vaccination.

from OCD. See Resp't's Mot., filed July 23, 2013, at 4; Pet'r's Prehear'g Br., filed Sept. 30, 2013, at 7.

In spring 2007, Mr. Spahn was completing the eighth grade at Cornerstone Christian Academy. His grades were a mixture of A's, B's, C's and one D+. Exhibit 10 at 3; see also id. at 4-5 (results of Stanford test).

On June 19, 2007, Mr. Spahn saw Jay Thakkar, a pediatrician, for a physical examination in anticipation of entering ninth grade. Dr. Thakkar reported that Mr. Spahn was feeling well and did not identify any significant health concerns. Dr. Thakkar also recommended a tetanus vaccination. Exhibit 11 at 1-2. Mr. Spahn received a dose of the Td vaccination on that day. Exhibit 5 at 1. Mr. Spahn, on the day of vaccination, was 67.3 inches tall and weighed 147 pounds. Exhibit 11 at 1.

It appears that no additional medical records were created during the remainder of the summer 2007. However, records written within the following year provide retrospective information about Mr. Spahn's condition.

According to a record created at the end of November 2007, [redacted]. Exhibit 2 at 46.[5] [Redacted] in records created in December 2007, [redacted].

Also, according to an April 2008 report, in "this summer," Mr. Spahn "seemed to have developed fairly abrupt onset of more severe [OCD] symptoms." Exhibit 12 at 12. Given that this report uses the term "this summer," it is unclear [redacted].

At the end of the summer 2007, Mr. Spahn started ninth grade at Cornerstone Christian Academy. Many records indicate that Mr. Spahn's transition into high school was not easy. Per a report created in April 2008, in September 2007, Mr. Spahn "had a clear florid exacerbation of OCD symptoms involving a need to engage in repetitive behaviors, which became eventually fully consuming and prevented [him] from being able to complete schoolwork in his freshman year of high school." Exhibit 12 at 12. On October 10, 2007, the school

[5] This particular record states [redacted]. Exhibit 2 at 46.

warned that Mr. Spahn was earning poor grades. Exhibit 10 at 14. The ensuing report card showed that in the first quarter for the school year, Mr. Spahn's grades were two B+'s, one C+, one C, one D- and one F. Exhibit 7 at 5. Mr. Spahn later told a social worker that around this time he was having thoughts of suicide. Exhibit 2 at 46.

On October 10 and 17, 2007, Mr. Spahn saw D. Russell Bishop, a clinical psychologist. Dr. Bishop did not identify a specific reason for the referral. Dr. Bishop stated that Mr. Spahn "exhibited repeated stereotypic movements with his hand and legs as well as with his head and neck. He exhibited facial tics." In Dr. Bishop's view, Mr. Spahn's "history is remarkable for the kinds of behavioral and social difficulties associated with pervasive developmental disorders. . . . [M]y impression [is] that he has Asperger's Disorder." Dr. Bishop recommended various ways for Mr. Spahn to cope with this disease. Exhibit 6.

On November 30, 2007, Mr. Spahn's father brought him to an emergency room at Lutheran General Hospital "due to an increase in OCD [symptoms] and stress at home [with] his mother." Lutheran General Hospital transferred him, via ambulance, to Chicago Lakeshore Hospital. Exhibit 2 at 35.

The intake assessment for Chicago Lakeshore Hospital indicates that Mr. Spahn had been "showing signs of decompensation in the last 3 months following a tetanus shot preceding the start of high school." Mr. Spahn "was recently diagnosed [with] Asperger's syndrome and suffers with social isolation. [His] current living situation [with] his mother and sister is stressful which has exacerbated his OCD and Asperger's syndrome." Mr. Spahn "recently decided not to return to school." Id.

The social history portion reports that Mr. Spahn "resides [with] his mother and sister [and his] [p]arents are divorced." Mr. Spahn "reported a past [history] of [redacted]."[6] Id.

Mr. Spahn remained in Chicago Lakeside Hospital from November 30, 2007, to December 13, 2007. Exhibit 2 at 3 (discharge summary). Throughout

[6] [Redacted].

this time, Mr. Spahn participated in individual, group, and family counseling. Often, Mr. Spahn described [redacted]. E.g. exhibit 2 at 23.[7] Another recurrent issue was whether Mr. Spahn's mother would consent to a prescription for Lexapro.[8] At discharge, the diagnoses were autistic spectrum disorder, OCD, and tic disorder. Id. at 3.

Following his discharge, Mr. Spahn saw Thomas Kirts, a psychiatrist. Dr. Kirts recorded that Mr. Spahn's mother, who was present for his evaluation, stated that he "felt worse after he received a DPT shot early last summer, he had no history of vaccinations prior to that and she is very unhappy about the doctor giving that without her okay." Exhibit 12 at 6.[9] Dr. Kirts observed verbal tics and tic-like movements in Mr. Spahn's hand and face. Dr. Kirts diagnosed Mr. Spahn as suffering from OCD, Tourette's syndrome, and Asperger disorder. The last two diagnoses were provisional in that they were based on a history. Id.

In January 2008, Mr. Spahn started seeing Dr. Joel Shepperd at the Center for Integral Health. As part of the intake history, which appears to have been provided by Mr. Spahn's father, [redacted], there is a note "tic[]s from vaccination" and a statement that Mr. Spahn received one vaccine (tetanus) "8/07. Trouble started." Exhibit 9 at 1-2. At the end of January 2008, Mr. Spahn started to attend DeKalb High School. Exhibit 5 at 17.

On April 1, 2008, Mr. Spahn saw Elizabeth Berry-Kravis, who appears to be a pediatric neurologist. The history obtained by Dr. Berry-Kravis is extremely thorough and reports Mr. Spahn's troubles in elementary school. She stated that Mr. Spahn had motor tics. She recommended adjustments in his medications. Exhibit 12 at 11-13.

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[7] On one occasion, his mother stated that she "believes that general immunizations . . . caused his school refusal and abnormal [behaviors]." Exhibit 2 at 21.

[8] Lexapro or escitalopram oxalate is used for the treatment of major depressive disorder. Physician's Desk Reference 1302-03 (58th ed. 2004).

[9] Although Dr. Kirts's record mentions that the vaccination included pertussis ("P"), Dr. Thakkar administered only a tetanus-diphtheria vaccine.

Although Mr. Spahn has filed more medical records from after 2008, the parties have not extensively relied upon them in briefing. However, Mr. Spahn stated that he is currently being followed by a neurologist, Dr. Withrow. Pet'r's Prehear'g Br., filed Sept. 30, 2013, at 7; see exhibit 57.

II. Procedural History

Mr. Spahn filed his petition on June 12, 2009.[10] It was accompanied by two medical records. The petition alleged that "Forrest was injured as a result of receiving a tetanus / dip[h]theria vaccination." Pet. ¶ 3. It also alleged that Mr. Spahn was diagnosed with OCD, Tourette's syndrome, and Asperger's disorder. Id. ¶ 8.

After Mr. Spahn filed additional medical records, the Secretary filed her report pursuant to Vaccine Rule 4. The Secretary maintained that Mr. Spahn had not established that he was entitled to compensation because, among other problems, an expert did not opine that the Td vaccine can cause tics. Resp't Rep't, filed April 23, 2010, at 13-14. Consequently, Mr. Spahn was ordered to file an expert report.

Approximately one year later, on April 25, 2011, Mr. Spahn filed a two-page report from Dr. Jubelt. Dr. Jubelt asserted that "[i]n the summer of 2007, [Mr. Spahn] developed an acute onset of severe symptoms of OCD with repetitive behaviors and motor tics." Exhibit 14 at 2 ¶ 5. Dr. Jubelt stated that the tetanus-diphtheria vaccine contained thimerosal and thimerosal-containing vaccines can cause tics. Id. at 2 ¶ 6.

On May 12, 2011, the Secretary filed information suggesting that the tetanus-diphtheria vaccine that Mr. Spahn had received contained only a trace amount of thimerosal and clarified that the types containing more were not marketed in the United States. Exhibit A (Food and Drug Administration, Vaccines, Blood & Biologics: Thimerosal in Vaccines (last visited May 10, 2011))

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[10] Technically, Lori Hessler, Mr. Spahn's mother filed the petition on behalf of Mr. Spahn. After Mr. Spahn reached the age of majority, the case was recaptioned to reflect Mr. Spahn's status as the petitioner. Order, filed Apr. 3, 2013.

at 8.[11] The Secretary suggested that the minimal amount could not cause an adverse reaction.[12]

On August 10, 2011, Mr. Spahn filed six items. The first two concern the amount of thimerosal. Exhibit 15-16. The next item was Dr. Jubelt's second report, stating that the tetanus-diphtheria vaccine contained 25 µg per 0.5 mL dose. Dr. Jubelt reasserted his opinion that the thimerosal in the vaccine caused an adverse reaction in Mr. Spahn. Exhibit 17. Dr. Jubelt cited three articles, which constitute the remainder of the August 10, 2011 submission. These are exhibit 17-1 (Nick Andrews et al., Thimerosal Exposure and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association, 114 Pediatrics 584 (2004)); exhibit 17-2 (Institute of Medicine Immunization Safety Review Committee, Immunization Safety Review: Thimerosal Containing Vaccines and Neurodevelopmental Disorders (Kathleen Stratton et al. eds., National Academy Press 2001)); exhibit 17-3 (Thomas Verstraeten et al., Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases, 112 Pediatrics 1039 (2003)).

In the ensuing status conference, the Secretary questioned Dr. Jubelt's reliance on the epidemiological articles. Mr. Spahn was instructed to review the epidemiological studies with Dr. Jubelt and also to ask Dr. Jubelt to present a medical theory explaining how the Td vaccine can cause tics, as required by Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Order, filed Sept. 1, 2011.

On January 12, 2012, after receiving two enlargements of time, Mr. Spahn filed a third report from Dr. Jubelt, which is essentially one page. Dr. Jubelt made

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[11] The Secretary filed two documents labeled exhibits A and B on May 12, 2011, then later filed a second exhibit A (Dr. Johnson's report) and B (Dr. Johnson's CV) on May 9, 2012. Although the original exhibit A is not discussed further in this decision, citations to Dr. Johnson's report will be noted as "exhibit A (Dr. Johnson's report)" for clarity.

[12] The Secretary accepted Dr. Jubelt's assertion that the vaccine that Mr. Spahn received contained 25 µg of mercury for purposes of the motion for summary judgment. Resp't's Mot. at 15. The Secretary had presented other evidence indicating that Mr. Spahn received much less than 25 µg of mercury, but is not relying upon this evidence.

two points. He first asserted that thimerosal can cause DNA breaks. Dr. Jubelt did not connect DNA breaks to tics. But, he cited one article discussing thimerosal and DNA breaks. Exhibit 18-1 (David Baskin et al., Thimerosal Induces DNA Breaks, Caspase-3 Activation, Membrane Damage, and Cell Death in Cultured Human Neurons and Fibroblasts, 74 Toxicological Sciences 361 (2003)). Second, Dr. Jubelt asserted that thimerosal can deplete the amount of glutathione available in the brain. Dr. Jubelt also cited one article for this proposition, exhibit 18-2 (S.J. James et al., Neurotoxicity is Associated with Glutathione Depletion: Protection with Glutathione Precursors, 26 NeuroToxicology 1 (2005)). Although there are unexplained gaps in Dr. Jubelt's report, it appears that depletion in glutathione can lead to neurodevelopmental disabilities and it appears that these neurodevelopmental disabilities may include tics. Exhibit 18.

The Secretary responded to Dr. Jubelt's three reports by submitting a report from Dr. Johnson (exhibit A) and a report from Dr. Kohrman (exhibit C) on May 9, 2012. Dr. Johnson discussed the Baskin and James articles. Exhibit A (Dr. Johnson's report) at 3-4. Dr. Johnson asserted that the amount of thimerosal used in the Baskin and James studies far exceeded the amount received by Mr. Spahn. Id. at 3-4.

Dr. Johnson stated that the epidemiological studies Dr. Jubelt cited, Verstraeten and Andrews, "are not relevant to this case. All of these studies focused on children who had a full set of vaccinations within the first year of life and were looking at outcome measures up to 10 years later. Since the patient in the present case did not receive any vaccination in the first year of life, the studies are not valid scientific comparisons." Exhibit A (Dr. Johnson's report) at 2. Dr. Johnson also remarked that the researchers doubted the causal connection between thimerosal and tics. Id.

Dr. Kohrman's criticisms were similar. According to Dr. Kohrman,

> there is no evidence that a single 25 µg dose of thimerosal in any individual infant, let alone that of a 13 year old with a mature nervous system[,] has any detrimental effects. Not only is the dose mostly sequestered in the muscle at the injection site, but it is diluted more than 10 fold by the patient's size alone compared to an infant.

Exhibit C at 3. Dr. Kohrman also noted that the Andrews epidemiological study "does not apply to [Mr. Spahn] as it examined exposure to thimerosal in the first few months of life." Id.

In addition, Dr. Kohrman introduced to this proceeding the idea that Mr. Spahn "had a history of developmental delay and obsessive compulsive symptoms prior to the vaccination in June of 2007." Id. The parties, as noted above, have accepted Dr. Kohrman's interpretation of Mr. Spahn's distant medical history.

To address Dr. Johnson's and Dr. Kohrman's reports, Dr. Jubelt was instructed to file a supplemental report, addressing specific questions. Order, filed May 22, 2012. Dr. Jubelt responded. Exhibit 19.

Because the Secretary had retained a toxicologist, Mr. Spahn retained a toxicologist, too. On October 22, 2012, Mr. Spahn filed a report from Dr. Aposhian. Exhibit 20. A large portion of Dr. Aposhian's report was devoted to explaining a genetic mutation, known as CPOX4. For this aspect, Dr. Aposhian relied upon an article by Woods that studied children who had (and did not have) a CPOX4 mutation. Id. at 9-13 (citing James S. Woods et al., Modification of neurobehavioral effects of mercury by a genetic polymorphism of coproporphyrinogen oxidase in children, 34 Neurotoxicology and Teratology 513 (2012)). Another portion of Dr. Aposhian's report discussed a report of a 5 year old Chinese boy who developed tics after using a herbal spray containing mercury about 20 times a day for four weeks. Id. at 7-8 (citing Albert Li et al., Mercury intoxication presenting with tics, 83 Archives Disease Childhood 174, 174-75 (2000)).

Dr. Aposhian concluded Mr. Spahn "received 25 µg mercury in the vaccine. It is probable that he is genetically CPOX4 hypersusceptible to mercury, therefore[,] he reacted to the mercury in thimerosal. . . . 25 µg of mercury would be expected to be toxicologically challenging to an adolescent with CPOX4." Id. at 13-14.

The final report was an answer to Dr. Aposhian's report in which Dr. Johnson stated that "Dr. Aposhian's speculation . . . hold[s] no scientific merit." Exhibit F at 2. In regard to the Li paper, Dr. Johnson found that report irrelevant. He stated "if this acute high dose exposure to mercury is necessary to cause tics and/or Tourette's syndrome, it is completely irrelevant and cannot, in any way, be

compared or analogous to a patient receiving an intramuscular injection of thimerosal." Id.

The Woods paper, according to Dr. Johnson, "is also scientifically irrelevant to this case." Dr. Johnson stated the children in the Woods study were "exposed chronically to elemental mercury vapor from the dental amalgam." Id. In contrast, Mr. Spahn was "exposed to a dose of mercury in the Td vaccine by intramuscular injection making any of the data generated in this paper meaningless." Id. at 2-3.

Dr. Johnson's final criticism was "[t]he most audacious claim by Dr. Aposhian is that, based on this paper, it is probable that Forrest Spahn is genetically CPOX4 hyper-susceptible to mercury and that the 25 µg of mercury that Forrest Spahn received in the Td vaccine would be toxic." Dr. Johnson continued: "This is a complete fabrication that is not supported by the data provided or any other published data." Dr. Johnson listed several reasons, including the ability to test for the CPOX4 polymorphism. Id. at 3.

Procedurally, the next step was setting the case for a hearing, which was scheduled for June 27-28, 2013. The parties were ordered to file briefs before the hearing. The order stated that the experts would be restricted to testifying about what had been disclosed in their reports. Order, filed Feb. 13, 2013, at 2. The order also alerted Mr. Spahn that he may need to file supplemental reports from Dr. Jubelt and/or Dr. Aposhian. Id. at 2 n.1, at 5 n.5. The order also noted that the parties may wish to explore settlement.

The parties attempted to resolve the case with the assistance of the chief special master. On May 1, 2013, the Secretary filed a status report, indicating that the parties had reached an agreement in principle. Consequently, a 15-week order was issued. This order provided time for the officials possessing the authority to bind the government to review the proposed settlement. About one month later, the Secretary reported that "the authorized representatives of the Attorney General have declined to grant settlement authority for the proposed tentative settlement in this matter." Resp't's Status Rep't, filed June 3, 2013.

The lack of a settlement agreement caused the case to be scheduled for a hearing again. In the process of planning for the hearing, the Secretary asserted that the case lacked a reasonable basis to proceed to a hearing. Order, filed June 20, 2013, at 1. Nevertheless, the case was set for a hearing on November 14-15, 2013. Order, filed July 1, 2013. The parties were again required to file prehearing

briefs. Order, filed July 2, 2013. The July 2, 2013 order repeated that Mr. Spahn may wish to file supplemental reports from Dr. Jubelt and/or Dr. Aposhian. This order also directed the Secretary to set forth her position regarding the reasonable basis to proceed to a hearing. Id. at 8-9.

The scheduling of the hearing prompted the submission of briefs on three overlapping topics. First, on July 23, 2013, the Secretary filed the pending motion for summary judgment. The essence of this motion is that Mr. Spahn has not established the reliability of Dr. Jubelt's and Dr. Aposhian's opinions such that a hearing would be warranted. Mr. Spahn filed an opposition to this motion on August 23, 2013, and the Secretary filed a reply on September 12, 2013.

The second topic was a motion requesting an award of attorneys' fees and costs on an interim basis, filed by Mr. Spahn on August 30, 2013. Mr. Spahn argued that he had demonstrated that he had a reasonable basis to proceed to hearing. On September 12, 2013, the Secretary filed an opposition to this motion, arguing that Mr. Spahn's case lacked a reasonable basis and "petitioner is therefore not entitled to recover any fees or costs." Resp't's Resp. at 2. This motion for interim fees remains pending.

The third topic was the submission of prehearing briefs as ordered on July 2, 2013. Mr. Spahn, after an unexplained delay, filed his prehearing brief on September 30, 2013. Mr. Spahn's prehearing brief clarified that he is claiming a significant aggravation of his pre-existing OCD. Pet'r's Prehear'g Br. at 1, 11.[13]

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[13] Earlier in the case, Mr. Spahn appeared to be claiming and Dr. Jubelt appeared to be opining that the June 2007 vaccination caused Mr. Spahn's OCD. See Pet. ¶ 3; exhibit 14 at 2 ¶ 8. But, after Dr. Kohrman reviewed Mr. Spahn's records and opined that Mr. Spahn suffered from OCD before the vaccination, Mr. Spahn's claim implicitly changed from one alleging that the vaccine caused OCD to one alleging the vaccination significantly aggravated the OCD.

While Mr. Spahn recognized this shift as his prehearing brief asserts only a significant aggravation claim, it is not entirely clear that Dr. Jubelt has grasped the difference. He seems to be assuming that Mr. Spahn did not have OCD before the vaccination. See exhibit 19 at 1 (Dr. Jubelt: "[a] few weeks after vaccination [Mr. Spahn] developed an acute onset of severe Obsessive Compulsive disorder").

If Mr. Spahn is proceeding on the theory that the Td vaccination significantly aggravated his OCD, then the typical course of OCD is important. Mr. Spahn may recover only if his OCD after vaccination is worse than his OCD would have been without the vaccination. See Locane v. Sec'y of Health & Human Servs., 99 Fed. Cl. 715, 730 (2011), aff'd, 685 F.3d 1375 (Fed. Cir.

Although Mr. Spahn has submitted many briefs since July 2, 2013, Mr. Spahn has not filed any additional evidence.

On October 9, 2013, Mr. Spahn moved for a continuance of the scheduled hearing to allow him the opportunity to pursue genetic testing for the CPOX4 gene variant that is the basis for Dr. Aposhian's opinion. This request was granted and Mr. Spahn was ordered to file a status report identifying when the results would be expected. Order, filed Oct. 11, 2013. On November 11, 2013, Mr. Spahn filed a status report indicating the testing would be available in spring 2014. Mr. Spahn was ordered to file a status report on any arrangements made for the CPOX4 testing. Order, filed June 4, 2014. In a status conference on July 8, 2014, Mr. Spahn indicated he was unable to obtain the genetic testing. Both parties indicated that they did not want to file additional evidence. Accordingly, the Secretary's motion for summary judgment is ready for adjudication.

III. Standards for Adjudicating Motions for Summary Judgment

Submissions to the Vaccine Program "may include a motion for summary judgment, in which event the procedures in RCFC 56 will apply." Vaccine Rule 8(d). RCFC 56 states "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."

"'[I]n determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the party opposing the motion, with doubts resolved in favor of the opponent.'" Rembrandt Data

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2012); Harris v. Sec'y of Health & Human Servs., No. 10-322V, 2014 WL 3159377, at *21 (Fed. Cl. Spec. Mstr. June 10, 2014), mot. for review filed (July 10, 2014). The orders for pre-trial briefs alerted Mr. Spahn about the need for a report from Dr. Jubelt on the expected course of OCD. Order, filed July 2, 2013, at 2 n.2, 6 n.6. However, Mr. Spahn has not presented any information from Dr. Jubelt or otherwise.

The absence of evidence about the anticipated course of OCD constitutes a serious omission in Mr. Spahn's case. Dr. Kohrman opined that tics often are manifestations of OCD. Exhibit C at 3. As the record stands, Dr. Kohrman's opinion is not rebutted. If Dr. Kohrman's opinion were accepted, then Mr. Spahn could not prevail on his claim that the Td vaccination made his OCD worse than it would have been but for the vaccination.

The Secretary, however, has not raised this potential deficiency in her motion for summary judgment. Thus, it is not a basis for granting the Secretary's motion.

Technologies, LP v. AOL, LLC, 641 F.3d 1331, 1336 (Fed. Cir. 2011), quoting Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1315 (Fed. Cir. 1998). The Federal Circuit has also explained "[w]hen a motion for summary judgment is properly supported by documentary and testimonial evidence, however, the nonmoving party may not rest upon mere allegations or denials of his pleadings, but rather, must present significant probative evidence to establish a genuine issue of material fact." Id., citing Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986). "Summary judgment may only be granted when no 'reasonable jury could return a verdict for the nonmoving party.'" High Point Design LLC v. Buyers Direct, Inc., 730 F.3d 1301, 1311 (Fed. Cir. 2013), quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

A genuine dispute of material fact precluding summary judgment is not created with conclusory statements from experts. Intellectual Science and Technology, Inc. v. Sony Electronics, Inc., 589 F.3d 1179, 1184 (Fed. Cir. 2011) (affirming grant of summary judgment because an expert's statement was not sufficiently detailed to identify allegedly infringing features); Zelinski v. Brunswick Corp., 185 F.3d 1311, 1317 (Fed. Cir. 1999) (affirming grant of summary judgment when non-moving party presented only a conclusory statement that there was infringement under the doctrine of equivalents). The Federal Circuit has articulated why naked statements from experts are not sufficient to withstand summary judgment:

> Under modern summary judgment law, a patentee who fails to provide probative evidence of infringement runs the risk of being peremptorily nonsuited. . . . Evidence from which a reasonable fact-finder could find infringement will forestall this possibility. However, a party does not meet this evidentiary threshold merely by submitting the affidavit of an expert who opines that the accused device meets the claim limitations. . . . The necessity for such an explicit factual foundation should be self-evident. If all expert opinions on infringement or noninfringement were accepted without inquiry into their factual basis, summary judgment would disappear from patent litigation.

Novartis Corp. v. Ben Venue Laboratories, Inc., 271 F.3d 1043, 1050-51 (Fed. Cir. 2001).

This reasoning is not limited to patent cases. "[I]n vaccine cases, as in other cases, summary judgment is summary judgment." Jay v. Sec'y of Health & Human Servs., 998 F.2d 979, 983 (Fed. Cir. 1993). In contexts other than patent litigation, the Court of Federal Claims has scrutinized the evidence opposing a motion for summary judgment. See, e.g., George Family Trust v. United States, 97 Fed. Cl. 625, 634 (2011) ("Plaintiff's evidence [that Army Corps of Engineers caused flooding], however, leaves gaping holes of logic in its chain of causation that are illuminated by the new declarations submitted by defendant"); Standard Federal Bank v. United States, 62 Fed. Cl. 265, 288-89 (2004) (finding that plaintiff's expert model could not support a claim for lost profits because the model was not based upon a "study of detailed and specific facts"); Applied Companies v. United States, 37 Fed. Cl. 749 (Fed. Cl. 1997) (finding that government could withhold payments on one contract due to overpayments on another contract), aff'd, 144 F.3d 1470 (Fed. Cir. 1998).

The principle that an expert's conclusory assertion does not prevent summary judgment is also reflected in cases in which the plaintiffs claim exposure to chemicals caused them an injury.[14] The Secretary cites a few examples, although Mr. Spahn did not address any of them. Resp't's Br. at 14-15 (citing Henrickson v. ConocoPhillips Co., 605 F.Supp.2d 1142 (E.D. Wash. 2009) (citing McCalin v. Metabolife Int'l, Inc., 401 F.3d 1233, 1241-42 (11th Cir. 2005), Mitchell v. Gencorp, Inc., 165 F.3d 778 (10th Cir. 1999); Wintz v. Northrop Corp., 110 F.3d 508 (7th Cir. 1997); Allen v. Pennsylvania Eng'g Corp., 102 F.3d 194 (5th Cir. 1996)) and Burleson v. Texas Dep't of Criminal Justice, 393 F.3d 577, 586 (5th Cir. 2004)).

Among the cases, Henrickson presents the most similar facts. There, a gasoline truck driver alleged occupational exposure to benzene and benzene-containing products caused his acute myelogenous leukemia. Henrickson, 605 F.Supp.2d at 1179. To support his theory, the plaintiff relied upon a toxicologist. However, the court excluded the toxicologist's testimony because he did not "pay

[14] Drawing guidance from decisions outside the Vaccine Program is appropriate because the standard for summary judgment is substantively similar. Simanski v. Sec'y of Health & Human Servs., 671 F.3d 1368, 1379 (Fed. Cir. 2012) (motions for summary judgment are governed by Rule 56 of the Rules of the Court of Federal Claims, which is substantively similar to Rule 56 of the Federal Rules of Civil Procedure).

careful attention to the dose-response relationship." Id. at 1157. The court further stated that the toxicologist did not use the generally accepted methodology in calculating the typical dosage. Id. at 1165.

Although rare, summary judgment has been used in Vaccine Program cases. See Jay, 998 F.2d at 983 (finding that "the parties are not disputing nor is there any dispute as to any facts material to the issues" and holding appellants were entitled to summary judgment); Rickard v. Sec'y of Health & Human Servs., No. 09-729V, 2011 WL 1979601 (Fed. Cl. Spec. Mstr. April 11, 2011) (granting summary judgment because "Petitioners' evidence, including medical records and the letter from [the vaccinee's] treating physician, is insufficient to satisfy the elements necessary to establish causation-in-fact"); Browning v. Sec'y of Health & Human Servs., No. 02-0929V, 2010 WL 1407973 (Fed. Cl. Spec. Mstr. March 19, 2010) (granting summary judgment when "[t]he medical opinion Petitioner submitted was unsupported by scientific data, lacked indicia of reliability, and, moreover, did not state the vaccinee's neurologic problems were caused by thimerosal-containing vaccines"). In adjudicating a motion for summary judgment in the Vaccine Program, "the special master can decide whether the petitioner's evidence is sufficient to allow the matter to proceed to a hearing." Simanski, 671 F.3d at 1382.

IV. Analysis

A. Overview of Mr. Spahn's Claim that Vaccines Containing Thimerosal Can Cause Tics

Mr. Spahn claims that a single dose of the tetanus-diphtheria vaccine containing 25 µg of mercury given to him at age 15 significantly aggravated his pre-existing OCD by causing tics. This description of Mr. Spahn's claim incorporates many details about the facts of his case that are relevant to resolving the pending motion for summary judgment.

Without the details, Mr. Spahn's basic claim boils down to an assertion that a mercury-containing vaccine can cause tics. For this proposition, Mr. Spahn has some support. His experts opine that mercury-containing vaccines can cause tics,

relying upon two studies --- Verstraeten (exhibit 17-3) and Andrews (exhibit 17-1).[15]

Verstraeten

For this study, the researchers divided their study into two phases. The first phase relied upon information from two health maintenance organizations, labeled HMO A and HMO B. In these two HMOs, approximately 120,000 infants received vaccines containing thimerosal. Depending upon the specific combination of vaccines, an infant may have received as much as 187 µg of mercury by the end of seven months. To avoid confounding factors, the researchers excluded the infants who had pre-existing health problems.

The researchers looked to see whether any infants developed any neurological problems. They calculated the relative risk at three different ages (one, three, and seven months).[16] These measuring points correspond to increasing exposure to mercury. For tics, the relative risk was statistically significant in HMO A at three months. For HMO B, the relative risk for tics was below 1.0 at three months. Data for the four other measuring points were mixed.

Following phase I work at HMO A and HMO B, researchers conducted a similar study in phase II at HMO C. HMO C had approximately 16,000 infants. The results for tics were not statistically significant.

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[15] Dr. Aposhian cites these two studies as well as two reports by Dr. Geier and Mr. Geier. Exhibit 20 at 18. However, Mr. Spahn did not cite to the Geier studies in his briefing. Mr. Spahn's apparent lack of reliance on those studies is appropriate because, in the recent decade, special masters have universally rejected the Geiers' work. See King v. Sec'y of Health & Human Servs., No. 03-584V, 2010 WL 5470787, at *7 (Fed. Cl. Spec. Mstr. Dec. 13, 2010); Masias v. Sec'y of Health & Human Servs., No. 99-697V, 2009 WL 1838979, at *39-41 (Fed. Cl. Spec. Mstr. June 12, 2009), mot. for review denied, slip. op. at 11 (Fed. Cl. Dec. 10, 2009), aff'd, 634 F.3d 1283 (Fed. Cir. 2011).

[16] A relative risk less than 1.0 means there is no effect on the incidence of disease. Watson v. Sec'y of Health & Human Servs., No. 96-639, 2001 WL 1682537, at *12 n.21 (Fed. Cl. Spec. Mstr. Dec. 18, 2001). A relative risk greater than 2.0 demonstrates legal probability. Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1320 (9th Cir. 1995).

With respect to tics, Verstraeten and colleagues stated that "[t]he results between HMOs, however, were not consistent. Our study encompassed a large number of separate analyses and, by chance alone, at least some associations would be expected to be statistically significant." Id. at 1044. Overall, the researchers recommended more investigations. Id. at 1046.

Andrews

After the Verstraeten group recommended additional studies, a group of British researchers continued the exploration into whether thimerosal-containing vaccines could cause neurological problems. Exhibit 17-1 at 584. They studied more than 100,000 children in the United Kingdom who received the only vaccines given to infants in the United Kingdom that contain thimerosal, the diphtheria-tetanus acellular pertussis ("DTaP") vaccine or the diphtheria-tetanus ("DT") vaccine . Id. Information about the participants was stored in the General Practice Research Database ("GPRD"). The GPRD contains medical histories of patients who visit any of more than 500 general practitioners, representing more than 3.4 million patients. The GRPD also allowed researchers to exclude from the study any children with pre-existing problems. Id. at 585.

The researchers stated that the GPRD indicates that a "substantial population" of infants received DTaP or DT at two, three, and four months. Id. at 587. Since each dose contains 50 µg thimerosal (25 µg of mercury), the child was exposed to 150 µg thimerosal (75 µg of mercury) by four months. This amount, according to Andrews and colleagues, is "similar to" the amount American children typically receive. Id. at 590.

Researchers looked for neurologic problems based on the children's exposure to thimerosal-containing vaccines. Exposure was defined by the number of DTaP or DT doses received at 3 months and 4 months. The researchers also established a hazard ratio per exposure to the vaccine.[17] The researchers found a

[17] A hazard ratio is used in epidemiological studies to compare two populations with hazard functions by dividing the risk of a particular event by the baseline risk. Gerald Van Belle, Statistical Rules of Thumb, 130 (2nd ed. 2008). If the hazard ratio is less than one, the second group is less affected than the first. Stanton Glantz, Primer of Bio-statistics, 388 (4th ed. 1997). If the hazard ratio is greater than one, the second group is more affected than the first. Id. If the hazard ratio is one, the groups are affected at equal rates. Id.

greater hazard risk for tics in infants who received three doses of the vaccine before one year. Additionally, all of the neurologic problems were more common in boys than girls. Besides the one analysis of tics, the researchers did not find evidence of an association between neurological disorders and thimerosal-containing vaccines. Id. at 589-90.

The researchers seemed to question the link between thimerosal and tics. They stated "Although the possibility of a true effect of thimerosal on minor transient tics cannot be ruled out, it is more plausible that the association found is a chance effect or the result of confounding." Id. at 590.

In this litigation, the Verstraeten study and the Andrews study underlie the opinions of Dr. Jubelt and Dr. Aposhian. Exhibit 19 at 2; exhibit 20 at 18. Both of Mr. Spahn's experts cite to these studies as supporting the conclusion that thimerosal-containing vaccines can cause tics. These opinions carry sufficient reliability that they would be sufficient to withstand summary judgment.

B. The Secretary's Arguments that Mr. Spahn Cannot Prevail on this Theory in this Case

The Secretary's motion for summary judgment is not directed against the general theory that thimerosal-containing vaccine can cause tics. Rather, the motion argues that Mr. Spahn cannot prevail on his claim because "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1345 (Fed. Cir. 2010). Mr. Spahn's claim, as previously stated, involves (1) a single dose of the Td vaccine (2) containing 25 µg of mercury, (3) given to an adolescent (4) already suffering from OCD.

To establish the required "reputable medical or scientific explanation" for how the Td vaccine can cause tics in the circumstances of this case, Mr. Spahn relies upon (1) Verstraeten and Andrews, (2) Baskin and James, as well as (3) miscellaneous studies to demonstrate his theory of the case. These topics are discussed below.

Verstraeten and Andrews

With support from Dr. Kohrman and Dr. Johnson, the Secretary argues that the Andrews and Verstraeten studies do not provide meaningful information about

this case. Dr. Kohrman and Dr. Johnson opined that the Andrews and Verstraeten studies analyzed people much different from Mr. Spahn. In his report, Dr. Johnson stated "[s]ince the patient did not receive any vaccinations during the first year of life, the studies are not valid scientific comparisons." Exhibit A (Dr. Johnson's report) at 2. Dr. Johnson further quoted the portion of Andrews that questioned whether their study truly established a causal relationship between thimerosal and tics. Id. at 7. Dr. Kohrman also found Andrews unpersuasive, stating, "This paper does not apply to [Mr. Spahn] as it examined exposure to thimerosal in the first few months of life." Exhibit C at 3. Relying upon these differences, the Secretary contends the studies cited by Dr. Jubelt and Dr. Aposhian "are irrelevant and the conclusions cannot be applied to petitioner's case." Resp't's Mot. at 16. This is important because "studies provide no evidence pertinent to persons not within the parameters of the test group." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010).

The first set of differences concerns the amount of mercury. The children in Andrews and Verstraeten received doses of vaccines amounting to at least 125 µg of mercury. In contrast, Mr. Spahn received only one dose containing 25 µg. Exhibit 17 at 1. The difference in dosage is an undisputed fact between the parties. The difference in dosage is also significant. "[T]he dose-response relationship remains central to the science of toxicology." Dwyer v. Sec'y of Health & Human Servs., No. 03-1202V, 2010 WL 892250, at *81 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). Likewise, "[s]everal appellate courts have held that an expert who seeks to opine on specific causation must pay careful attention to the dose-response relationship." Henrickson, 605 F.Supp.2d at 1157 (citing McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1241-42 (11th Cir. 2005); Mitchell v. Genocorp, Inc., 165 F.3d 778, 781 (10th Cir. 1999)). For more information about the dose-response relationship, see David L. Eaton, Scientific Judgment and Toxic Torts --- A Primer in Toxicology for Judges and Lawyers, 12 J. L. & Pol'y 5, 15 (2003).

In a supplemental report, Dr. Jubelt attempted to address the 25 µg dose of mercury. His total response was that 25 µg "is not a trace amount, and it is a significant enough dose to cause an adverse effect such as suffered by Forest Spahn." Exhibit 17 at 1. However, the Secretary effectively argued against this assertion. "Dr. Jubelt does not cite a single source for this statement. While he has submitted a number of medical articles with his reports, upon inspection none of them provide reliable support for his opinion." Resp't's Mot. at 16. Dr. Jubelt's assertion amounts to no more than a classic "I said it" statement that does not have to be accepted on summary judgment. "It is well-established that unsupported

expert opinions do not create a genuine issue of material fact." Minkin v. Gibbons, P.C., 680 F.3d 1341, 1352 n.5 (Fed. Cir. 2012) (citing Davis v. Brouse McDowell, 596 F.3d 1355, 1364 (Fed. Cir. 2010) (citing Novartis Corp. v. Ben Venue Labs, Inc., 271 F.3d 1043, 1051 (Fed. Cir. 2001) (applying Third Circuit law)).

In addition to the difference in dosage, the children in the Verstraeten and Andrews studies and Mr. Spahn also have a difference in size. When asked to respond to Dr. Kohrman's and Dr. Johnson's assertions that the amount of mercury is relatively smaller for Mr. Spahn because he weighed more than an infant, Dr. Jubelt stated "Forrest's size would tend to protect him from thimerosal toxicity." Exhibit 19 at 3.[18] Additional confirmation that the effect of an exposure depends, in part, on body weight comes from the studies relied upon by Dr. Jubelt. Exhibit 17-1 (Andrews) at 584; exhibit 17-3 (Verstraeten) at 1040, 1045).

The third set of differences concerns the age. The children in the Andrews and Verstraeten studies were less than one year old when they received the mercury from the vaccine. Conversely, Mr. Spahn was 15 years old. The difference in age is significant. "Other factors that may affect toxicity of a specific substance include… the age." Dwyer, 2010 WL 892250 at *81. Dr. Aposhian previously testified that it takes an infant four times longer than an adult to rid a chemical. Id. at *81 n.334. Furthermore, Dr. Kohrman asserted that "a 13 year old [has] a mature nervous system." Exhibit C at 3. When asked to respond, Dr. Jubelt did not contradict this assertion.

A fourth set of differences concerns the health of the people exposed to mercury. The children in the Andrews and Verstraeten studies were healthy whereas Mr. Spahn already suffered OCD. The difference in health is significant. Dwyer, 2010 WL 892250 at *81 (determining that the "health status" is another factor that may affect toxicity of a specific substance).

These four differences are based upon undisputed facts. After Dr. Kohrman and Dr. Johnson pointed out the problems with using Verstraeten and Andrews as a basis for extrapolation about Mr. Spahn, exhibit A (Dr. Johnson report) at 2 and exhibit C at 3, Dr. Jubelt could have presented some basis for relying upon

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[18] Dr. Jubelt added that the anoxia that Mr. Spahn suffered at birth may have increased his vulnerability. Anoxia is discussed below.

Verstraeten and Andrews. However, Dr. Jubelt did not express an opinion about why Verstraeten and Andrews provided meaningful information about Mr. Spahn. Dr. Jubelt even accepted some distinctions Dr. Kohrman and Dr. Johnson identified. See exhibit 19. In the absence of any assertions from Dr. Jubelt, there is no genuine dispute that the collective differences between the studies and Mr. Spahn are so great that any attempted extrapolation from Verstraeten and Andrews to Mr. Spahn is not reasonable. The Andrews and Verstraeten studies do not support Dr. Jubelt's opinion that one dose of Td vaccine containing 25 µg of mercury can cause tics in a 15 year old.

In the same report in which Dr. Jubelt largely did not defend his use of Verstraeten and Andrews, Dr. Jubelt took a different course. Rather than relying upon epidemiologic studies, Dr. Jubelt attempted to present a theory explaining how the Td vaccine can cause tics. Dr. Jubelt relied on the Baskin and James studies of cell tissue cultures. Exhibit 19 at 2 ¶ c, 3 ¶ e.

Baskin

Dr. Jubelt cited a 2003 study by Baskin et al. as evidence that "[t]himerosal also has been shown to cause DNA breaks" and that "DNA is the road map for synthesizing compounds." Exhibit 18 at 2. David A. Baskin and colleagues studied thimerosal toxicity using a combination of fluorescent techniques to monitor membrane degradation, DNA damage, and cell death in fibroblast[19] and neuronal cell cultures exposed to micromolar[20] amounts of thimerosal at several time points. Exhibit 18 (Baskin) at 3-4. Although many concentrations between 125 nM and 250 µM were included in the test, no cell membrane or DNA damage was observed in the cells exposed to less than 1 µM of thimerosal. Thus, the study concluded that 1 µM (405 µg/l(kg)) of thimerosal was the lowest concentration observed to induce detectable toxic effects in cell culture. Id. at 6.

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[19] Fibroblasts are flat, elongated connective tissue cells. Dorland's at 701.

[20] Molar (M or mol/kg(l)), as in micromolar (µM (M x 10^{-6}) or nanomolar (nM, M x 10^{-9}), is a measure of the concentration of a solute, expressed as the number of moles of solute per liter of solution. Dorland's at 1172. Micromoles are 1/100,000 of a mole. Nanomoles are 1/1,000,000,000 of a mole.

Baskin et al. estimated the 1 μM concentration of thimerosal as nearly four to six times that contained in a course of immunizations administered to infants between birth and six months. Id. at 6-7.

James

Dr. Jubelt also cited to a study by James et al. from 2005. Dr. Jubelt's discussion of this study is limited to a single sentence: "Because thimerosal can bind to proteins, it can result in brain cell toxicity (both neurons and glial cells), mediated by glutathione depletion." Exhibit 18 at 1-2. As discussed below, Dr. Jubelt's characterization appears inconsistent with the results observed by James et al. and is contrary to the author's intended interpretation.

James et al. designed an experiment to exploit thimerosal's characteristic affinity for thiol groups to propose a mechanism for protecting cultured cells when exposed to an acute dose of thimerosal. James et al. treated two different cultured cell lines with various chemicals for one hour before introducing 15 μM of thimerosal. As predicted, the cytotoxicity of thimerosal was greatly reduced in the treated cells compared to untreated cells. Exhibit 18 at 15.

The authors proposed that their research might promote treatments for pregnant or elderly recipients of thimerosal-containing vaccines. Jones et al. were careful to define the limits of their results stating: "Acute high dose exposures to [t]himerosal (μmol/L) in cultured cells were used to study mechanistic aspects of [t]himerosal toxicity and **not intended to mimic exposures of developing brain cells in vivo to [t]himerosal in vaccines (nmol/kg).**" Exhibit 18 at 13 (emphasis added). This passage indicates that the thimerosal concentration used in the study was measured in micromoles (μmol/kg(l)), while the concentration of thimerosal of a vaccine dose would be in the nanomolar range (nmol/kg(l)). As pointed out in footnote 20, micromoles are a thousand times larger than nanomoles.

Dr. Johnson described Dr. Jubelt's opinion relying on the Baskin and James papers as "fatally flawed and has no scientific validity." Exhibit A (Dr. Johnson's report) at 3. Dr. Johnson said that due to the experimental design and dosing used in the Baskin and James studies, described above, it is "impossible" to relate them to Mr. Spahn's case. Id.

Dr. Johnson described the great difference between the doses studied in Baskin and James from the dose that Mr. Spahn received as a significant problem.

Exhibit A (Dr. Johnson's report) at 3. Mr. Spahn's weight at the time he received the Td vaccine dose containing 25 µg of thimerosal (12.375 µg of inorganic mercury at 49.5% concentration) was 147 lbs. (approx. 67 kg). Exhibit 11 at 1. The concentration of mercury Mr. Spahn was exposed to (0.185 µg/l(kg)), is less than one thousandth of the minimum concentration at which Baskin et al. observed toxicity (201 µg/l(kg)). Dr. Johnson has explained, without contradiction, that the amounts of thimerosal tested by Baskin and James greatly exceeded what is given to infants (and the amount given to infants exceeds on a relative basis the amount given to a 15 year old). Dr. Johnson states, again without contradiction, that the cells in the James study are being hit with a "sledge hammer." Exhibit A (Dr. Johnson's report) at 3.

In response to Dr. Johnson's rebuke of the thimerosal doses used in the Baskin and James studies, Dr. Jubelt agreed that "Forrest's size would tend to protect him from thimerosal toxicity." Exhibit 19 at 2. Dr. Jubelt clarified that beyond that protection, it was Mr. Spahn's "vulnerable brain" and "mild chemical imbalance" that made him vulnerable to the effects of thimerosal. Id. However, Dr. Jubelt did not provide an explanation describing his reason for this conclusion about vulnerability.[21]

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[21] Although not significant in the consideration of the Secretary's motion for summary judgment, Dr. Johnson underscored that the studies' use of self-replicating and de-differentiated cells in culture, while cost efficient, rendered any relation of the data to actual *in vivo* cell behavior "impossible." Exhibit A (Dr. Johnson's report) at 3.

Dr. Jubelt described studies based on cell lines as the "basis for understanding" disease pathogenesis and treatment. Exhibit 19 at 3. However, Dr. Jubelt did not describe how studies like Baskin and James that provide such a basis, could be interpreted to reach a conclusion about the effects of the thimerosal Mr. Spahn received.

Dr. Johnson's opinion regarding the (lack of) usefulness of cell line studies comports with the view expressed in a publication from the Federal Judicial Center. The Federal Judicial Center has published a series of guides designed "to assist judges . . . in reaching an informed and reasoned assessment concerning the basis of expert evidence." Jerome P. Kassirer & Gladys Kessler, Preface, in Reference Manual on Scientific Evidence (Federal Judicial Center, 3d ed. 2011). A pertinent guide contained therein provides criteria for assessing the reliability of in vitro tests, including reproducibility and adoption of the protocol by a reputable organization such as the National Institutes of Health. Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology, in Reference Manual on Scientific Evidence 633, 645-47 (Federal Judicial Center, 3d ed. 2011). Neither the Baskin nor James study fits the reliability criteria described.

Miscellaneous Studies

In response to the Secretary's brief criticizing the articles underlying Dr. Jubelt's opinion, Mr. Spahn was expected to present a strong defense demonstrating the reliability of the opinion. Mr. Spahn's opposition does not rehabilitate Dr. Jubelt's opinion. The substance of Mr. Spahn's brief is a series of block quotations from articles cited by Dr. Jubelt. Pet'r's Opp'n at 11-12 (quoting exhibits 14, 17). While the articles themselves constitute evidence, "there is nothing in Dr. Jubelt's reports that discusses the cited portions of these articles." Resp't's Reply at 4. Mr. Spahn's references to these articles were contained in an attorney's brief in response to a motion for summary judgment. The attorney's argument does not compensate for the lack of explanation from either Dr. Jubelt or Dr. Aposhian about the articles' significance. A special master does not have to address articles not explained by an expert. Moberly v. Sec'y of Health & Human Servs., 85 Fed. Cl. 571, 605-06 (Fed. Cl. 2009), aff'd, 592 F.3d 1315 (Fed. Cir. 2010).

In any event, the passages Mr. Spahn has quoted do not help support the claim that a single dose of 25 µg of mercury to a 15-year-old with OCD can cause tics. The two studies that discuss thimerosal-containing vaccines and tics, Andrews and Verstraeten, have been discussed above. The remaining studies are not on point. For example, Mr. Spahn quoted an article saying "symptoms [of skin reactions] can occur at low levels of mercury exposure." Pet'r's Br. at 9 (quoting exhibit 14-2 (Stephan Bose-O'Reilly et al., Mercury Exposure and Children's Health, 40 Current Problems Pediatric Adolescent Health Care 186, 197 (2010)). Skin reactions are not tics. And, this portion is extracted from a section of the article on chronic exposure to mercury.

Mr. Spahn also cites another case report mentioned in the Bose-O'Reilly paper that appears to present acute mercury exposure in a child, but the ensuing symptoms were not tics. Pet'r's Br. at 10 (quoting exhibit 14-2 (Bose-O'Reilly) at 198). This particular case involved a child that was "exposed to a 'silvery liquid' for four months" and experienced "bilateral lower extremity pain resulting in abnormal gait, burning sensation and pain in both hands and feet, headache, dizziness, nausea, constipation, decreasing appetite and mood lability." Exhibit 14-2 (Bose-O'Reilly) at 198. Again, this case report provides no support for Mr. Spahn's claim. The child's exposure to mercury (assuming the silvery liquid was mercury) occurred continually for months prior to the onset of symptoms and the ensuing reaction (assuming it was a reaction) was not at all like tics.

Mr. Spahn argues that his thimerosal dose-exposure level exceeded the Environmental Protection Agency's ("EPA") maximum daily dose for mercury. Pet'r's Opp'n at 10.[22] However, the EPA report itself is neither in the record nor discussed by any expert. Resp't's Reply at 3 n.2. While Mr. Spahn's brief suggests an exposure above the EPA's maximum daily dose for mercury might cause tics, this is only an assertion of counsel. Creative Compounds, LLC v. Starmark Laboratories, 651 F.3d 1303, 1311 (Fed. Cir. 2011) (attorney's statements made in the absence of evidence failed to raise a genuine issue of material fact).

To recap, Mr. Spahn has presented some evidence that multiple exposures to thimerosal-containing vaccines given to infants may cause tics. But, the Secretary has attacked the reliability of extrapolating from those studies to Mr. Spahn. Mr. Spahn has not answered these challenges (and Dr. Jubelt may have even accepted them as valid points). If there were reliable evidence to construe in Mr. Spahn's favor, Mr. Spahn would be entitled to every reasonable inference. Conceivably, Dr. Jubelt could have presented some basis for extrapolating studies of infants to someone who is 15 years old. Likewise, Dr. Jubelt conceivably could have argued why the Baskin and James studies are informative. If Dr. Jubelt had presented any reliable basis for these inferences, then his opinion could withstand summary judgment. Dr. Jubelt's silence on these points carries legal importance.

C. Petitioner's Rebuttal

Mr. Spahn presents two arguments to explain why he is different. In Mr. Spahn's view, he is vulnerable to mercury toxicity for two reasons. First, he suffered anoxic damage at birth. Pet'r's Br. at 10. Second, he was allegedly born with a CPOX4 genetic mutation. Pet'r's Br. at 13.

It is true that Mr. Spahn needed oxygen at birth. Exhibit 3 at 22, 31-36. Whether Mr. Spahn suffered lasting damage is less clear. Regardless, it is true that Dr. Jubelt asserts in his fourth report that "his vulnerable brain from anoxia (lack of oxygen) at birth as well as a mild chemical imbalance (mild ADD or OCD

[22] Although Mr. Spahn cites to exhibit 17 for the EPA standard, exhibit 17 does not contain this information.

signs) noted in grade school would probably make him much more vulnerable to the acute effects of thimerosal." Exhibit 19 at 2 ¶ b. However, Dr. Jubelt provides no support for the assertion that a temporary anoxia at birth would make him especially vulnerable to mercury in a vaccine given to him 15 years later. Thus, Mr. Spahn's attempt to raise his lack of oxygen as a material fact that would preclude summary judgment has no effect.

Mr. Spahn's second distinction concerns the CPOX4 gene. Dr. Aposhian's report is largely devoted to reviewing the CPOX4 gene. See exhibit 20 at 9-13. In his report, Dr. Aposhian relies upon the 2012 Woods study in which the children were exposed to mercury vapor.[23] Exhibit 20 at 9-13 (citing Woods (2012)). There are at least two problems with Dr. Aposhian's report. First, there is no basis for assuming, as Dr. Aposhian does, that Mr. Spahn has the CPOX4 gene. In the absence of information about Mr. Spahn's genetic status, Dr. Aposhian engages in circular reasoning. He states that Mr. Spahn adversely reacted to mercury because he had the genetic mutation. For proof of the genetic mutation, Dr. Aposhian cites his purported adverse reaction. Courts have found circular reasoning from experts unreliable. In re Meridia Products Liability Litig., 328 F.Supp.2d 791, 805 (N.D. Ohio 2004) (excluding expert); Mancuso v. Consolidated Edison Co. of New York, Inc., 968 F.Supp. 1437, 1450 (S.D.N.Y. 1997) (same); cf. Stone v. Sec'y of Health & Human Servs., 676 F.3d 1373, 1383 (holding special master was not arbitrary in relying upon an expert's hearing testimony because the expert did not engage in circular logic), reh'g en banc denied, 690 F.3d 1380 (Fed. Cir. 2012), cert. denied, 133 S.Ct. 2022 (2013); Holmes v. Sec'y of Health & Human Servs., 115 Fed. Cl. 469, 490 (2014) (holding special master was not arbitrary in rejecting the opinion

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[23] According to the Secretary, Dr. Aposhian's hypersusceptibility theory in this case is "essentially the same" as the theory Dr. Aposhian presented and three special masters rejected in the OAP cases. Resp't's Mot. at 18; see Dwyer, 2010 WL 892250 at *85-108, 167-68; King v. Sec'y of Health & Human Servs., No. 03-584V, 2010 WL 892296, at *45-54 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); Mead v. Sec'y of Health & Human Servs., No. 03-251V, 2010 WL 892248, at *56-62 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Mr. Spahn disagrees. Mr. Spahn says Dr. Aposhian presented a theory that children suffered "mercury efflux disorder." Pet'r's Opp'n at 13 (citing Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 331968, at *21-23 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), mot. for review denied, 89 Fed. Cl. 158 (2009), aff'd, 617 F.3d 1328 (Fed. Cir. 2010)).

Although the special masters in those cases exhaustively analyzed whether children can be hypersusceptible to mercury, this case is being analyzed on its own facts. Thus, the Secretary's argument does not need to be resolved.

of an expert who engaged in circular reasoning); Dodd v. Sec'y of Health & Human Servs., 114 Fed. Cl. 43, 57 (2013) (same).

While Mr. Spahn could have solved this evidentiary gap by obtaining a genetic test, and was given months to pursue genetic testing and did not do so, even a positive report would not address the second flaw in Dr. Aposhian's report. Much like the problem with Dr. Jubelt, Dr. Aposhian is relying upon a study whose participants and their outcomes greatly differ from Mr. Spahn and what is alleged to have happened to him. As Dr. Johnson noted, in contrast to Mr. Spahn, the children with a CPOX4 mutation who reportedly performed poorly in various neurobehavioral aspects were "chronically exposed to elemental mercury vapor from the dental amalgam." Exhibit F at 2 (citing Woods (2012)).

Again, if Dr. Aposhian said why a chronic exposure is like a single exposure, there could be an issue requiring further exploration at hearing. But, Dr. Aposhian has not. This is a variation on the dose-response argument the Secretary raised with Dr. Jubelt. Because the dose-response principle comes from toxicology, the Secretary argued that "Dr. Aposhian, and not Dr. Jubelt, is in the better position to address the issue of dose-response, given their respective areas of expertise." Resp't's Reply, filed Sept. 12, 2013, at 4. Since Dr. Aposhian has not spoken on this important issue, Mr. Spahn is unable to demonstrate why a chronic exposure to mercury is like a single exposure.

D. Is Summary Judgment Appropriate?

The opinions from both Dr. Jubelt and Dr. Aposhian suffer from deep flaws. The ensuing question is whether the case should proceed to a hearing despite such deficiencies.

The Secretary raised the dose-response relationship throughout the litigation. Less than one month after Dr. Jubelt's first report, the Secretary challenged Dr. Jubelt's assumption about the amount of mercury in the Td vaccine and argued that the dose was insufficient to cause harm. Reports from the Secretary's experts maintained the theme that Dr. Jubelt's failure to account for differences in exposures left his opinion unsupported and unreliable. See Exhibit A (Dr. Johnson's report) at 4; exhibit C at 3.

These criticisms required a response. But Dr. Jubelt never brought forth a credible reason for relying upon the studies involving vastly different doses. Mr. Spahn has not demonstrated the reliability of Dr. Jubelt's opinion.

The dose-response issue also presents a problem with respect to Dr. Aposhian's opinion. The Li article reported a single case of a boy developing tics after being exposed to mercury 20 times a day for four weeks. Similarly, the children in the Woods article were chronically exposed to mercury through their dental amalgams.[24]

At the end of the day, none of the articles provides a basis for finding that either Dr. Jubelt or Dr. Aposhian has offered a reliable opinion that a single dose of the Td vaccine can cause tics in a 15-year-old adolescent. While Mr. Spahn cannot be required to submit medical literature, Althen, 418 F.3d at 1281, he is required to demonstrate the reliability of his expert's opinions. Cedillo v. Sec'y of Health & Human Servs., 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing Vaccine Rule 8(b)(1)). The Secretary's experts consistently challenged the reliability of Mr. Spahn's experts. After the Secretary incorporated these criticisms into the motion for summary judgment, Mr. Spahn and his experts were obligated to respond. However, the experts did not provide any basis for finding their opinions reliable. When the patently distinguishable articles are stripped away, Mr. Spahn's opposition to summary judgment is really nothing more than "naked" assertions by expert witnesses. The Federal Circuit has consistently held in patent cases that conclusory statements are not sufficient to withstand summary judgment.

The reasons for granting summary judgment in cases like Intellectual Science, 589 F.3d at 1184; George Family Trust, 97 Fed. Cl. at 632; and Henrickson, 605 F.Supp.2d at 1179, support summary adjudications in the Vaccine Program. Although Vaccine Rule 3(b)(2) requires each party to be afforded "a full and fair opportunity to present its case," this instruction must be read in conjunction with the possibility of summary judgment as provided in Vaccine Rule 8(d).

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[24] Mr. Spahn also has not presented any evidence that he has a CPOX4 genetic mutation like the children in the Woods study.

Here, Mr. Spahn has enjoyed "a full and fair opportunity" to present opinions from Dr. Jubelt and Dr. Aposhian addressing the criticisms of their opinions. The most prominent example was the February 13, 2013 order for pre-trial submissions. Citing Simanski, 671 F.3d at 1382, the order informed Mr. Spahn that the experts' testimony would be limited to what the expert's reports disclosed. The order also permitted Mr. Spahn to file supplemental reports to disclose opinions from Dr. Jubelt and/or Dr. Aposhian that had not been provided previously. Nevertheless, Mr. Spahn did not provide additional reports or any other evidence. In addition, after the Secretary filed the pending motion for summary judgment, Mr. Spahn requested an opportunity to pursue testing for the CPOX4 mutation. See Pet'r's Mot. for Continuance, filed Oct. 9, 2013. Although Mr. Spahn did not file anything as a result of this process, Pet'r's Status Rep't, filed June 27, 2014, Mr. Spahn could have used this time also to obtain more information from either Dr. Jubelt and/or Dr. Aposhian. The lack of response from Dr. Jubelt and Dr. Aposhian suggests that they have nothing more to say, making a hearing unnecessary.[25]

As mentioned earlier, summary judgment in the Vaccine Program is rare but not unprecedented. Mr. Spahn's case, too, presents an unusual circumstance in

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[25] Not only is a hearing unnecessary, a hearing could be costly to Mr. Spahn. The Secretary has already argued that Mr. Spahn's case lacks a reasonable basis. Resp't's Resp., filed September 12, 2013, at 2. If there is no reasonable basis, Mr. Spahn cannot be awarded attorneys' fees and costs. 42 U.S.C. § 300aa—15(e); Chuisano v. United States, 116 Fed. Cl. 276 (2014).

The presence of Dr. Jubelt and Dr. Aposhian does not mandate a finding of reasonable basis because the Federal Circuit has found that a special master was not arbitrary or capricious in concluding that a case lacked a reasonable basis to proceed to a hearing despite an expert's testimony. Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 (Fed. Cir. 1994) ("Congress must not have intended every claimant, whether being compensated or not under the Vaccine Act, collect attorneys' fees and costs by merely having an expert state an unsupported opinion"). Here, the undisputed facts show that the opinions of Dr. Jubelt and Dr. Aposhian lack reliability and summary judgment is being granted for that reason. Summary judgment is not being granted for other questionable aspects of Mr. Spahn's claim. See footnotes 4 (potential pre-existing tics), 12 (amount of mercury in the vaccine), and 13 (expected course of OCD). These factors could influence the determination of reasonable basis if the case went to hearing. Thus, if this case went to a hearing, Mr. Spahn may incur the costs that the Vaccine Program will not reimburse.

which the opinions from his experts cannot be given a reasonable inference of soundness. Thus, summary judgment is appropriate.

V. Conclusion

The Secretary filed a motion for summary judgment and presented multiple reasons why Mr. Spahn's experts' opinions are not reliable. Mr. Spahn did not establish their reliability; thus, there is no material issue of fact precluding summary judgment.

Respondent's motion is GRANTED. The clerk's office shall enter judgment accordingly.[26]

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master

[26] Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by each party filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.