

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

LAUREN SHORTNACY,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

* No. 10-827V
* Special Master Christian J. Moran
*
* Filed: September 15, 2014
*
* Decision on the record; statute of
* limitations; insufficient
* proof of causation; human
* papillomavirus vaccine (“HPV”);
* nodular sclerosing Hodgkin’s
* disease.

Patricia Leigh O’Dell, Beasley, Allen, et al., Montgomery, AL, for petitioner;
Ann Martin, United States Dep’t of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION¹

Lauren Shortnacy filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa—10 through 34 (2006), on December 2, 2010. Ms. Shortnacy alleges that the doses of the human papillomavirus (“HPV”) vaccine she received on July 23, 2007, September 26, 2007, and January 28, 2008, caused her to suffer nodular sclerosing Hodgkin’s disease (“Hodgkin’s”).

In support of her claim, Ms. Shortnacy has submitted opinions from her experts, Michael McCabe, Ph.D., a toxicologist and immunologist, and Stephen L. Davidson, M.D., an oncologist. Dr. McCabe provided a theory to explain how the HPV vaccine could have caused Ms. Shortnacy’s Hodgkin’s. Dr. Davidson provided an opinion on the onset of Ms. Shortnacy’s Hodgkin’s in response to the

¹ The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa—12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

Secretary's argument that the case was untimely filed and barred by the Vaccine Act's statute of limitations. In opposition to Ms. Shortnacy's expert opinions, the Secretary offered the opinion of Kenneth L. McClain, Ph.D., M.D., an oncologist. In lieu of proceeding with a previously scheduled entitlement hearing, Ms. Shortnacy filed a motion for a ruling on the record on July 7, 2014. For the reasons set forth below, Ms. Shortnacy's petition is untimely and she has not demonstrated that she is entitled to compensation.

I. Background

A. Medical History

Ms. Shortnacy received doses of the HPV vaccine on July 23, 2007, September 26, 2007, and January 28, 2008. On November 21, 2007, Ms. Shortnacy went to a clinic where she reported a cough, congestion, sore throat, and swollen lymph nodes. Ms. Shortnacy did not complain of itchiness. Findings of Fact, issued Mar. 30, 2012, at 6.

On December 3, 2007, Ms. Shortnacy saw her pediatrician, Dr. Paris, where she complained of swollen lymph nodes in her neck area and dry, itchy skin. *Id.* By mid-December 2013, the swelling in Ms. Shortnacy's lymph nodes decreased, but her lymph nodes did not return to normal size. *Id.* at 11. After the swelling returned, Ms. Shortnacy saw Dr. Paris on January 7, 2008, complaining of swollen glands under her left armpit. *Id.* Ms. Shortnacy underwent a lymph node biopsy and was diagnosed with Hodgkin's on February 1, 2008. *Id.* at 11-12.

Ms. Shortnacy received treatment at the AFLAC Cancer Center and Blood Disorders Service at Children's Health Care of Atlanta and underwent six rounds of chemotherapy by July 2008. Exhibit 5 at 324. After completing chemotherapy, Ms. Shortnacy received treatment for intracranial hypotension and avascular necrosis. Exhibit 10 at 3-5, 14-16, 26. By her December 14, 2010 cancer survivor consultation, Ms. Shortnacy reported that she was doing well and studying nursing as a sophomore in college. *Id.* at 44.

B. Procedural History

The events associated with the prosecution of Ms. Shortnacy's claim are set forth in the sections below beginning with the factual development of her case followed by the submission of expert opinions and preparation for hearing.

1. Factual Development

In support of her December 2, 2010 petition, Ms. Shortnacy filed medical records (exhibits 1-10) on February 15, 2011, and March 31, 2011. Her February 15, 2011 filing also included an amended petition, changed only in marking her exhibits as numbered rather than lettered. A status conference was held on April 6, 2011, during which respondent indicated that Ms. Shortnacy's medical histories suggest her symptoms began prior to December 2007. In response, Ms. Shortnacy proposed providing an affidavit from Dr. Paris, her doctor in December 2007. Ms. Shortnacy was ordered to submit an affidavit from herself and Dr. Paris describing her condition before December 2007. Order, issued Apr. 6, 2011. Ms. Shortnacy filed the affidavits (exhibits 11-12) and a report from Dr. McCabe (exhibit 13) in early July 2011.

A status conference was held on July 11, 2011. During this conference, the Secretary again raised her concern over the timeliness of Ms. Shortnacy's petition and proposed a fact hearing to resolve the onset of her symptoms. Consequently, the parties began planning for a fact hearing.

Ms. Shortnacy filed additional records from Columbus Clinic and Acute Care on July 19, 2011 (exhibit 14). On August 19, 2011, Ms. Shortnacy filed a second amended petition in which she changed the characterization of her December 3, 2007 itching from "extreme" to "mild." Compare Pet., filed Dec. 2, 2010, ¶ 3 with 2d Am. Pet., filed Aug. 19, 2011, ¶ 3.

The Secretary assessed Ms. Shortnacy's claim in her report and concluded that Ms. Shortnacy was not entitled to compensation for two separate reasons. Resp't's Rep., filed Aug. 26, 2011, at 2. First, notwithstanding the shift in allegations from severe itching to mild itching, the Secretary concluded Ms. Shortnacy was displaying symptoms of Hodgkin's more than 36 months before she filed her petition. As such, the statute of limitations barred Ms. Shortnacy's petition. Id. at 11-13.

In addition to asserting that Ms. Shortnacy's petition was time-barred, the Secretary also concluded that Ms. Shortnacy failed to fulfill the criteria for a Vaccine Table injury, or demonstrate by a preponderance of the evidence her Hodgkin's was caused by the HPV vaccines she received. Id. at 13-16.

A status conference was held on September 1, 2011, during which the parties discussed proceeding with a November 2011 fact hearing in light of

respondent's Rule 4 report. In an order issued following the conference, Ms. Shortnacy was directed to file affidavits from herself and her mother detailing the severity of her fatigue from July to December 2007, and whether her itching started before December 3, 2007.

In response to the September 1, 2011 order, Ms. Shortnacy filed affidavits (exhibit 15-21), as well as school and employment records (exhibits 19-20). The affidavits generally described Ms. Shortnacy's fatigue and itching as beginning in late December 2007.

A factual hearing was held on November 1, 2011. Ms. Shortnacy, her mother, father, Dr. Paris, and a family friend testified via videoconferencing at the hearing. The parties completed submitting their posthearing briefs in February 2012.

On March 30, 2012, the findings of fact were issued stating that Ms. Shortnacy was experiencing "an unusual amount" of itchiness on December 3, 2007. Findings of Fact at 7. Additionally, Ms. Shortnacy's itchiness began prior to her December 3, 2007 visit. *Id.* at 9. These findings did not resolve the date of onset of Ms. Shortnacy's Hodgkin's disease.

2. Expert Opinions

As noted above, early in the case, Ms. Shortnacy filed a report from Dr. McCabe about causation (exhibit 13). In this report, Dr. McCabe opined that Ms. Shortnacy's Hodgkin's resulted from stimulation of her immune system by Virus-Like Particles ("VLPs") and the alum adjuvant contained in the HPV vaccine. Exhibit 13 at 5-8. Dr. McCabe concluded that the VLPs and adjuvant "promoted a favorable microenvironment... that promoted malignant transformation and/or survival of HRS cells thereby leading to [Ms.] Shortnacy's Hodgkin's lymphoma." *Id.* at 7.² Dr. McCabe additionally opined that it was reasonable to expect that the immune response generated by the HPV vaccine also transformed HRS cell precursors harboring latent Epstein-Barr virus ("EBV") into malignancies.³

² HRS, or Hodgkin Reed Sternberg, cells are a common histologic characteristic of Hodgkin's disease. Dorland's Illustrated Medical Dictionary 322 (32nd ed. 2012).

³ Dr. McCabe cited to Ms. Shortnacy's medical records documenting antibody reactivity to EBV and varicella zoster. Exhibit 13 at 2 (discussing exhibit 7 at 23).

Following an April 19, 2012 status conference, Ms. Shortnacy was ordered to file an expert report by July 18, 2012. Since Dr. McCabe is not a medical doctor, he lacked the qualifications to discuss when a disease began. Thus, Ms. Shortnacy needed to find a new expert. Order, issued Apr. 19, 2012. After three extensions of time, Ms. Shortnacy filed her report from Dr. Davidson on November 12, 2012 (exhibit 26).

In his report, Dr. Davidson stated that “my honest assessment is that Lauren likely systemically developed Hodgkin's disease prior to November 2007” and that, in his opinion, “the first clearly established symptoms and manifestations of the onset of the disease” was in early January 2008. Exhibit 26 at 3.

A status conference was held on January 30, 2013, during which the Secretary raised again the issue of timeliness and requested a supplemental report from Dr. Davidson regarding symptom onset. Ms. Shortnacy was ordered to file a supplemental report as the Secretary requested. Order, issued Jan. 31, 2013. For this report, Ms. Shortnacy was instructed to have Dr. Davidson address the undersigned's March 30, 2012 Findings of Fact and to clarify whether Ms. Shortnacy's December 3, 2007 symptoms (swollen lymph nodes and dry, itchy skin) were manifestations of the onset of her Hodgkin's disease. Id.

In his supplemental report (exhibit 28, filed Feb. 26, 2013), Dr. Davidson maintained that Ms. Shortnacy's early January 2008 symptoms, not her December 3, 2007 symptoms, were the first onset symptoms of her Hodgkin's disease. Exhibit 28 at 1.

During a status conference held on March 5, 2013, the Secretary stated that she intended to file a report from Dr. McClain, an oncologist, responding to Dr. Davidson's onset opinion. Ms. Shortnacy was ordered to provide this report to Dr. Davidson and report his initial impressions at the next status conference. Order, issued Mar. 5, 2013.

On April 16, 2013, the Secretary filed the report on onset from Dr. McClain (exhibit B). In his report, Dr. McClain concluded that “the lymphadenopathy and pruritus present on 12-3-2007 were most likely symptoms of Hodgkin lymphoma.” Exhibit B at 2.

During the status conference following Dr. McClain's report, the Secretary stated that bifurcating the statute of limitations issue from the causation issue was

not necessary. The Secretary offered to file a report from Dr. McClain on the issue of causation. Order, issued May 2, 2013.

In his second report (exhibit E, dated June 19, 2013), Dr. McClain strongly opposed Dr. McCabe's immune stimulation theory. Dr. McClain opined that while immune stimulating cells surrounding pathologic HRS cells do impact their survival, this is secondary to the primary cause of Hodgkin's: multiple genetic mutations in key cell signaling pathways. Exhibit E at 1. Dr. McClain disagreed with Dr. McCabe's opinion that immunizations prompt the production of signals from immune cells that can cause Hodgkin's. Rather, Dr. McClain stated that the multiple genetic mutations that cause Hodgkin's also paralyze the very same immune system signaling on which Dr. McCabe relied. Furthermore, Dr. McClain indicated that Dr. McCabe's HRS cell proliferation theory was not genetically possible given the fact that HRS cells do not possess functional versions of the necessary genes. Id. at 3.

Dr. McClain cited to literature for evidence that EBV's role in stimulating HRS cell malignancies is secondary to genetic events that occur prior to viral infection. Id. (citing exhibit X (Enrico Tiacci et al., Analyzing primary Hodgkin and Reed-Sternberg cells to capture the molecular and cellular pathogenesis of classical Hodgkin lymphoma, 120(23) *Blood* 4609 (2012)). Moreover, Dr. McClain stated that although Ms. Shortnacy's records indicate a past EBV infection, there was no evidence for assuming that EBV had a role in causing her Hodgkin's without Epstein-Barr Encoded RNA ("EBER") staining of her lymph node biopsy to document the presence of EBV in her HRS cells.

In response to Dr. McClain's report, Ms. Shortnacy was ordered to file a responsive report from Dr. McCabe as well as a status report on the availability of a pathology sample for EBER staining. Order, issued July 16, 2013. Ms. Shortnacy reported that she had ordered the requested pathology slides and arranged for their storage. Pet'r's Status Rep., filed Aug 28, 2013.

On August 30, 2013, Ms. Shortnacy filed a supplemental report from Dr. McCabe (exhibit 33) in which he argued that Dr. McClain had mischaracterized his immune stimulation theory. Exhibit 33 at 2. Dr. McCabe clarified that he did not suggest that the HPV vaccine could cause Hodgkin's by giving rise to B cell mutation. Id. Dr. McCabe asserted that Dr. McClain ignored "a large body of research and scientific consensus that inflammation is a promoter in the process of carcinogenesis[,]" but provided no citation to such research. Id. at 2. Dr. McCabe then restated his theory that Ms. Shortnacy's Hodgkin's was caused by an HPV

vaccine-elicited immune response which triggered malignancy in HRS precursor cells. Dr. McCabe cited studies by Frazer and Pinto et al. as evidence of the immune response elicited by HPV vaccination. Id. at 3 (citing exhibit 34 (Ian Frazer, Correlating immunity with protection for HPV infection, 11 (Supp. 2) Int'l J. Infectious Diseases S10 (2007); exhibit 35 (Ligia A. Pinto et al., HPV-16 L1 VLP vaccine elicits a broad-spectrum of cytokine responses in whole blood, 23 Vaccine 3555 (2005)).

On November 21, 2013, the Secretary filed a supplemental report from Dr. McClain (exhibit BB) responding to Dr. McCabe (exhibit 33). In this report, Dr. McClain asserts that Dr. McCabe's theory in which a potent vaccine response causes growth of lymphomas is "not scientifically reliable." Exhibit BB at 1. Dr. McClain also reviewed the literature cited by Dr. McCabe and provided interpretations contradicting those of Dr. McCabe. In particular, Dr. McClain found that the Pinto et al. study (exhibit 35), which Dr. McClain cited as evidence of an "active and ongoing" immune response following HPV vaccination, actually supports the opposite conclusion that immune responsive cells are in fact not continuously active.

Dr. McClain concluded that:

Ms. Shortnacy had a mutation in a germinal center B cell that became a Hodgkin Lymphoma cell. It activated the immune cells around it which supported the malignant cell with cytokines and chemokines[;] the malignant cells grew, migrated, and caused her Stage IIIA Hodgkin Lymphoma. [The HPV] immunization had nothing to do with this process[;] it was merely coincidental.

Exhibit BB at 3.

Ms. Shortnacy was ordered to file the EBER staining results as well as a status report indicating if Dr. McCabe would be filing a response to Dr. McClain. See order, issued Jan. 16, 2014. Ms. Shortnacy reported that an additional report from Dr. McCabe would not be helpful. Pet'r's Rep., filed Jan. 27, 2014. On February 12, 2014, Ms. Shortnacy filed a status report seeking "the Court's assistance in discussing additional avenues for mediation." Pet'r's Rep., filed Feb. 12, 2014.

Ms. Shortnacy filed the EBER test results (exhibit 42) on February 18, 2014. During a status conference held later that same date, the parties agreed to file

supplemental expert reports in light of the negative EBER results. Additionally, the parties discussed Ms. Shortnacy's request for mediation, to which respondent stated that she did not believe mediation would be productive considering petitioner's claim. Order, issued Feb. 19, 2014.

On March 4, 2014, the Secretary filed another supplemental report from Dr. McClain (exhibit EE) stating that the negative EBER result nullified Dr. McCabe's theory. Exhibit EE at 1 (discussing Dr. McCabe's report, exhibit 13 at 5). On March 21, 2014, Ms. Shortnacy filed a supplemental report from Dr. McCabe (exhibit 43) stating that the negative EBER result had no effect on his theory as it was never contingent on the presence of Epstein-Barr virus. Exhibit 43 at 1-2.

3. Preparation for Hearing

Pursuant to an earlier order, the hearing was set for June 19-20, 2014. Order, issued Oct. 9, 2013. The parties were ordered to file prehearing briefs in preparation for hearing. Order, issued Apr. 4, 2014. In this order for prehearing briefs, the undersigned detailed the issues of Ms. Shortnacy's case in regard to timeliness and the Althen prongs and directed the parties to address these issues in their briefs. The parties were directed to confirm that each of their experts had completely disclosed their opinions before the hearing, and to inform the court if additional supplemental reports were required. Id. The parties submitted their briefs by the end of May 2014.

On June 2, 2014, the undersigned issued an order stating that upon his review of the case material, including the parties' prehearing briefs, he had reached a tentative conclusion that petitioner was unlikely to prevail on either the timeliness of her petition or that the HPV vaccine caused her Hodgkin's. The undersigned discussed the weaknesses of Ms. Shortnacy's case including the disparity between the qualifications of the testifying witnesses. In light of the problems with Ms. Shortnacy's case, the undersigned expressed the concern that proceeding to a hearing might lack reasonable basis.

By the June 10, 2014 prehearing status conference, the hearing schedule had been slightly amended to accommodate Ms. Shortnacy's expert, Dr. Davidson.⁴ At that status conference, Ms. Shortnacy proposed that the undersigned provide a

⁴ Dr. Davidson was no longer able to testify on June 19-20, 2014, due to an unavoidable conflict.

decision on the statute of limitations issue before proceeding with a causation hearing. Additionally, Ms. Shortnacy acknowledged the difference in credentials between Dr. McCabe and Dr. McClain and stated that she may wish to retain an oncologist to opine on causation.

The Secretary opposed Ms. Shortnacy's proposal to retain an oncologist and stated that the difference between Dr. McClain's and Dr. McCabe's qualifications was not new and that considerable time and resources had already been invested in prosecuting Ms. Shortnacy's claim. Ms. Shortnacy requested the remainder of the day to consider whether to proceed with the hearing.

A follow-up status conference was held the next day. At this conference, Ms. Shortnacy confirmed that she did not want to proceed with the scheduled hearing and instead intended to file a motion for a ruling on the record. The Secretary did not object. See order, issued June 11, 2014.

On June 25, 2014, Ms. Shortnacy moved for a decision on the written record. In her motion, Ms. Shortnacy states that although she is able to demonstrate causation for her Hodgkin's, she "has decided not to move forward with a hearing." Pet'r's Mot., filed June 25, 2014, at 8.

Respondent filed a response stating "[a] preponderance of the evidence does not support a finding that petitioner's case was timely filed. Even assuming arguendo that petitioner's case were timely filed, there is not a preponderance of reliable scientific evidence to support a finding that petitioner's HPV vaccine(s) caused the development of her Hodgkin's Lymphoma." Resp't's Resp., filed July 7, 2014, at 18. Ms. Shortnacy did not file a reply to respondent's response. Accordingly, this case is now ready for adjudication.

II. Ruling on the Record

In establishing the Vaccine Program, Congress instructed the Court of Federal Claims to promulgate rules, including a rule for "the opportunity for parties to submit . . . evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings." 42 U.S.C. § 300aa—12(d)(2)(D). In accord with this statutory directive, "the special master may decide a case on the basis of written submissions without conducting an evidentiary hearing." Vaccine Rule 8(d).

The Court of Federal Claims has interpreted Congress' intent as not requiring routine oral presentations, but rather that interested parties be afforded only the opportunity to submit relevant written information. Hale v. Sec'y of Health & Human Servs., 22 Cl. Ct. 403, 407 (1991). Furthermore, the Vaccine Program was designed to "avoid hearings and dispose of cases quickly." Boley v. Sec'y of Health & Human Servs., 05-420V, 2008 WL 4615034, at *2 (Fed. Cl. Sept. 9, 2008), mot. for rev. denied, 86 Fed. Cl. 294 (2009).

Although a hearing was scheduled, Ms. Shortnacy stated that she did not want to proceed to trial and moved for a ruling on the record. Pet'r's Mot., filed June 25, 2014. The parties have had an opportunity to present their cases and the record is adequate for making a decision.

The procedural posture of the case is that of a ruling on the record, not a motion for summary judgment. As such, Ms. Shortnacy is not entitled to inferences in her favor. She must establish her case by preponderant evidence. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010). Ms. Shortnacy's claim for compensation is discussed below beginning with the timeliness of her petition, followed by a causation analysis.

III. Statute of Limitations

A living petitioner has 36 months to file a petition for compensation from the first symptom or manifestation of onset of an injury. 42 U.S.C. §300aa—16(a)(2) (2006). The statute of limitations can be triggered by either a symptom of the injury or a manifestation of onset, "whichever is first." Markovich v. Sec'y of Health & Human Servs., 477 F.3d 1353, 1357 (Fed. Cir. 2007).

The day of onset is excluded in calculating the statute of limitations and accrual begins the following day. Spohn v. Sec'y of Health & Human Servs., No. 95-0460V, 1996 WL 532610, at *3 (Fed. Cl. Spec. Mstr. Sept. 5, 1996) (determining the statute of limitations for claim based upon symptoms starting July 17, 1992, expired on July 17, 1995, and dismissing petition based upon a filing one day after the expiration of the statute of limitations), mot. for rev. denied in unpublished op. (Fed. Cl. Jan. 10, 1997), aff'd, 132 F.3d 52 (Fed. Cir. 1997) (table). Ms. Shortnacy filed her petition on December 2, 2010. In order for Ms. Shortnacy to have filed her petition within the statute of limitations, the first manifestation of onset must have occurred on or after December 2, 2007.

The medical field must recognize the symptom or manifestation of onset as part of the condition for which compensation is sought. Cloer v. Sec’y of Health & Human Servs., 654 F.3d 1322, 1335 (Fed. Cir. 2011) (en banc), cert. denied, 132 S.Ct. 1908 (2012). At least two symptoms could be viewed as heralding the onset of Ms. Shortnacy’s Hodgkin’s. These are swollen lymph nodes and itchiness. Exhibit B at 2-3; exhibit 26 at 2.

Ms. Shortnacy’s expert, Dr. Davidson, acknowledged that she “likely systemically developed Hodgkin’s disease prior to November 2007.” Exhibit 26 at 3. Dr. Davidson opined that the upper respiratory infection Ms. Shortnacy suffered in November 2007, was likely a result of her immune system being compromised by Hodgkin’s disease. Id. However, Dr. Davidson argues that Ms. Shortnacy’s Hodgkin’s was not “clinically apparent” until early January 2008, when her bloodwork showed atypical lymphocytes and her lymph nodes enlarged for the second time in association with pruritus and fatigue. Exhibit 26 at 3; exhibit 28 at 1.

In light of his opinion that Ms. Shortnacy’s disease likely began before November 2007, Dr. Davidson’s opinion regarding Ms. Shortnacy’s swollen lymph nodes is unclear. Ms. Shortnacy was observed to have swollen lymph nodes on November 21, 2007, and December 3, 2007. Exhibit 14 at 4; exhibit 2 at 62. Despite opining that her November 2007 infection was likely due to her Hodgkin’s, Dr. Davidson maintains that Ms. Shortnacy’s symptoms on November 21, 2007, were consistent with an infectious process and that her Hodgkin’s was not clinically apparent. Exhibit 26 at 3. Dr. Davidson does not dismiss Ms. Shortnacy’s swollen nodes on December 3, 2007, but instead states that her symptoms of January 2008 were “more clinically apparent” for diagnosing Hodgkin’s. Id. Dr. Davidson finds the swelling significant only in January 2008, when the swollen lymph nodes were also present in the axilla and they were accompanied by bloodwork showing atypical lymphocytes. Id.; exhibit 2 at 50-52; exhibit 3 at 4. Although Dr. Davidson provides some basis for not accepting Ms. Shortnacy’s November and December 2007 swollen nodes as the onset of her Hodgkin’s, he does not provide a basis for dismissing her December 2007 itchiness. See exhibit 26; see also exhibit 28.

Dr. Davidson’s silence regarding Ms. Shortnacy’s early December 2007 itchiness is a weakness. It is difficult to follow Dr. Davidson’s reasoning that Ms. Shortnacy’s disease began prior to November 2007, but was not clinically apparent until January 2008, despite complaints of similar symptoms in the two previous months.

On the other hand, the Secretary's expert, Dr. McClain, opined that Ms. Shortnacy's itchiness and swollen lymph nodes on December 3, 2007, were most likely symptoms of Hodgkin's. Exhibit B at 2. Dr. McClain cited to literature underscoring the importance of pruritus in diagnosing Hodgkin's. Id. (citing exhibit D (Paolo G. Gobbi et al., Reevaluation of Prognostic Significance of Symptoms in Hodgkin's Disease, 56 Cancer 2874 (1985) (identifying pruritus as an important finding in 10% of Hodgkin's cases)). In addition to establishing pruritus as a symptom, Gobbi et al. describe the type of itchiness as severe and resistant to local and systemic antipruritics, which Dr. McClain found to describe the itching Ms. Shortnacy experienced accurately. Id.

Additionally, Dr. McCabe, though not a doctor of medicine, described itchy skin as a symptom of Hodgkin's in a background summary of the disease compiled from major medical journals and texts. Exhibit 13 at 3 (citing exhibits 44-49). The literature cited by Dr. McClain and Dr. McCabe contradicts Dr. Davidson's implicit opinion that Ms. Shortnacy's December 3, 2007 itching was not a manifestation of her Hodgkin's. Thus, a preponderance of the evidence supports a finding that itchiness is a manifestation of Hodgkin's.

Since Ms. Shortnacy experienced an unusual amount of itchiness the morning of December 3, 2007, her itchiness must have begun prior to that date because it was bothersome enough to schedule a morning appointment with Dr. Paris.⁵ Exhibit 2 at 9; Findings of Fact at 7-9. Dr. McClain stated that by December 3, 2007, Ms. Shortnacy's itchiness had "intensified to the point where it was a major symptom." Exhibit B at 2. Dr. McClain's inference is persuasive and suggests that Ms. Shortnacy's itchiness began some time prior to her appointment. See exhibit 4 at 9 (February 20, 2008 statement that Ms. Shortnacy had "severe itching, November 2007"); Second Amended Ex. 2 at 7 (March 11, 2008 letter, stating "[a]t Thanksgiving 2007, [Ms. Shortnacy] noticed swelling in her leck neck area. She also developed pruritus"). Thus, Ms. Shortnacy's itchiness began before December 2, 2007.

⁵ In her motion, Ms. Shortnacy cites only to a portion of her hearing testimony in which she stated that the itchiness began after Christmas. Pet'r's Mot. at 2 (citing Tr. 26-28, 47-48). But, this testimony was not accepted in the ruling finding facts which determined that Ms. Shortnacy experienced an unusual amount of itchiness on December 3, 2007. See Findings of Fact, issued Mar. 30, 2012, at 7.

Because Ms. Shortnacy experienced her first manifestation of Hodgkin's (extreme itchiness and swollen lymph nodes) more than 36 months before she filed her petition, Ms. Shortnacy's petition was filed outside of the statute of limitations.⁶ This finding means that she is not entitled to compensation.

IV. Causation

Even if Ms. Shortnacy filed her petition within the time permitted by the statute of limitations, she has another hurdle. To receive compensation under the National Vaccine Injury Compensation Program, a petitioner must prove either 1) that she suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to the HPV vaccine, or 2) that she suffered an injury that was actually caused by a vaccine. See §§ 300aa—13(a)(1)(A) and 300aa—11(c)(1). An examination of the record did not uncover any evidence that Ms. Shortnacy suffered a "Table Injury."⁷ Further, Ms. Shortnacy does not argue that her Hodgkin's was significantly aggravated by the HPV vaccines.

The elements of Ms. Shortnacy's case were set forth by the Federal Circuit: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). The burden of proof is preponderance of the evidence. Id.

Under the Act, petitioners may not be awarded compensation based solely on the petitioner's claims alone. Rather, the petitioner's claims must be supported by either medical records or by medical opinion. 42 U.S.C. § 300aa--13(a)(1). Ms. Shortnacy relies on the opinion of Dr. McCabe. Pet'r's Mot., citing exhibits 13, 33, 43.⁸ The Secretary relies on the opinion of Dr. McClain. Resp't's Resp., citing exhibits B, E, EE.

⁶ Ms. Shortnacy has not claimed the she is entitled to equitable tolling of the statute of limitations.

⁷ No injuries are associated with any HPV vaccine. See 42 C.F.R. § 100.3.

⁸ Dr. Davidson has not expressed an opinion that the HPV vaccine caused Ms. Shortnacy's Hodgkin's.

In weighing the persuasiveness of opinion testimony, special masters may consider the background of the person offering the opinion. See Snyder v. Sec'y of Health & Human Servs., 553 F. App'x 994, 1000-02 (Fed. Cir. 2014) (special master's finding that respondent's experts were more persuasive due in part to their current practice in neurology compared to petitioner's expert who had no recent practice was not arbitrary or capricious); see also Locane v. Sec'y of Health & Human Servs., 99 Fed. Cl. 715, 727 (2011), aff'd, 685 F.3d 1375 (Fed. Cir. 2012).

Dr. McCabe's academic background has focused on topics other than diseases of the human lymph system. Dr. McCabe earned his Ph.D. in Microbiology and Immunology from Albany Medical College in 1991. He completed his postdoctoral research with the Karolinska Institute in Stockholm, Sweden in 1992, and then taught as an assistant professor at Wayne State University where he later served as the director of the school's flow cytometry center. Exhibit 13 at 2. Since 2000, Dr. McCabe has taught and conducted research "centered on mechanistic metal toxicology and immunotoxicology" at the University of Rochester School of Medicine and Dentistry. Id. at 1. As an associate and (later) adjunct professor in Rochester's Department of Environmental Medicine, Dr. McCabe has taught courses in metal toxicity, cell signaling, immunity, and ethics. Dr. McCabe has been a contributing author on approximately 40 peer-reviewed publications, many relating to the toxicity of metals. Dr. McCabe was the lead author on approximately 13 of these publications. Exhibit 13 at 18-21.

In 2009, Dr. McCabe joined Robson Forensic, Inc., where he is currently employed. At Robson, Dr. McCabe provides "technical investigations, analysis, reports, and testimony toward the resolution of commercial and personal injury litigation of toxicology" and "human health assessments" involving environmental and occupational exposures to metals, solvents and other agents. Id. at 1.⁹ Dr. McCabe's reports linking HPV vaccine to Hodgkin's appear to flow exclusively from his work as a professional testifying expert.¹⁰ Nothing in his curriculum

⁹ Dr. McCabe's CV does not indicate any vaccine related "agents" in the list of human health assessments he conducts through Robson Forensic, Inc.

¹⁰ The fact that Dr. McCabe's income is nearly completely derived from providing expert opinions has factored into assessments of his reliability. Godfrey v. Sec'y of Health & Human Servs., 10-565V, 2014 WL 3058353, at *22 (Fed. Cl. Spec. Mstr. June 11, 2014). Trial judges may apply the Daubert factors more rigorously when evaluating "for hire" experts. Johnson v.

(...continued)

vitae indicates that he studied Hodgkin's or related diseases previously. See exhibit 13.

Dr. McClain received his Ph.D. (1971) and M.D. (1972) from the University of Chicago School of Medicine. He completed his residency at The Johns Hopkins Hospital in Baltimore, MD in 1976. Exhibit C at 1.

Dr. McClain has coauthored more than 195 peer-reviewed articles, in 80 of which he was the primary author. Notably, Dr. McClain authored several "UpToDate" physician's reference articles including coauthoring the 2003 Hodgkin's Diseases article. Exhibit C at 22. Dr. McClain has received millions of dollars in research funding from sources such as the National Institutes of Health and the National Cancer Institute for his work in Langerhan's cell histiocytosis.¹¹ Id. at 5-9. He has lectured internationally on Hodgkin's (exhibit C at 45) and is a tenured professor in the Department of Pediatrics at Baylor College of Medicine and Director of the Histiocytosis Program at Texas Children's Cancer and Hematology Centers (exhibit C at 1, 3). Dr. McClain is currently practicing and has more than 34 years of experience caring for children with lymphomas and lymphoproliferative diseases caused by the Epstein Barr Virus. Exhibit B at 1-2.

Here, the difference in background is vast. Although Dr. McCabe has a background in toxicology, he is not a medical doctor. Exhibit 13. Dr. McClain, however, is an award-winning medical doctor who specializes in treating lymphoma. Exhibit C.

The difference in experience is reflected in the reports from the experts. The Secretary's expert, Dr. McClain, wrote reports that are among the best the undersigned has reviewed. The multitude of citations to peer-reviewed articles reflects an intimate familiarity with the subject of lymphomas, commensurate with more than three decades of work in the field of pediatric cancers. He is truly an expert, a source of information to other doctors treating patients.

Manitowoc Boom Trucks, Inc., 484 F.3d 426, 435 (6th Cir. 2007) (citing Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1316 (9th Cir. 1995)).

¹¹ Langerhan's cells are antigen-presenting cells found in the lymph nodes, among other places. Dorland's at 320. Langerhan's cell histiocytosis is defined as a malignancy-like overgrowth of Langerhan's cells. Robert M. Kliegman et al., Nelson Textbook of Pediatrics 1773 (19th ed. 2011).

In contrast, Ms. Shortnacy's expert, Dr. McCabe, qualifies as an expert in immunology on the basis of his Ph.D. and career experience, which has focused mainly on toxicological effects of metals. He has been found qualified to opine about immunology and toxicity of metals. Koehn v. Sec'y of Health & Human Servs., 11-355V, 2013 WL 3214877, at *32 (Fed. Cl. May 30, 2013), mot. for review denied sub nom. C.K. v. Sec'y of Health & Human Servs., 113 Fed. Cl. 757 (2013), appeal docketed, No. 14-5054 (Fed. Cir. Feb. 18, 2014); Snyder v. Sec'y of Health & Human Servs., 01-162V, 2009 WL 332044, at *19 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), mot. for review denied, 88 Fed. Cl. 706 (2009); Hazlehurst v. Sec'y of Health & Human Servs., 03-654V, 2009 WL 332306, at *11 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), mot. for review denied, 88 Fed. Cl. 473 (Fed. Cl. 2009), aff'd, 604 F.3d 1343 (Fed. Cir. 2010). But, in offering an opinion that a vaccine can and did cause a lymphoma, Dr. McCabe is leaving the fields of science where he is most knowledgeable.

Dr. McCabe's reports illustrate his relative lack of knowledge about lymphomas. Although Dr. McCabe cited articles throughout his reports, Dr. McClain has persuasively shown that Dr. McCabe took passages out of context and did not fully appreciate the nuances of the studies.

Flaws in Dr. McCabe's reports are apparent in all the Althen prongs. The first Althen prong asks whether the vaccine could cause the alleged injury. See Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir. 2006) (affirming special master's use of "can cause" and "did cause" as consistent with the Althen test); Veryzer v. Sec'y of Health & Human Servs., 100 Fed. Cl. 344, 352 (2011) (describing the first prong of Althen as presenting the question of general causation). Dr. McCabe's reports are convoluted and not easily summarized, but, essentially, he argues that the HPV vaccine causes the proliferation and survival of initiated HRS precursors which results in the proliferation of Hodgkin's lymphoma. Pet'r's Prehr'g Br. at 11 (citing exhibit 33 at 2).

But, Dr. McClain contradicts this postulate and asserts that it is "not scientifically reliable." Exhibit BB at 1. According to Dr. McClain, Ms. Shortnacy's Hodgkin's was a result of genetic mutations arising in her germinal B cells independent of vaccination and that these mutations forestalled the immune signals implicated in Dr. McCabe's theory. Id. at 2; exhibit E at 3-4. Dr. McClain challenged Dr. McCabe's claim that HPV vaccine could cause HRS cell proliferation since these cells lack functional genes necessary for such stimulation. Exhibit E at 3. Moreover, Dr. McClain summarily showed that Dr. McCabe's claim of EBV involvement was an incorrect assumption given current literature

and available laboratory analysis of Ms. Shortnacy's biopsy. Exhibit E at 3 (citing exhibit X (Tiacci)). Dr. McClain's awareness regarding EBER staining is also telling of his greater familiarity of the subject matter.

Another deficiency in Dr. McCabe's report is his opinion regarding timing, which corresponds to the third Althen prong.¹² Ms. Shortnacy must show that the first manifestation of her Hodgkin's occurred in a medically appropriate timeframe to infer causation. Dr. McCabe provided a vague opinion on timing stating that "the expected interval between vaccination and the onset of HL is predicted by the time period that measur[.]able changes in the immune response are known to be elicited by the vaccine." Exhibit 33 at 2-3. Dr. McCabe cited to the time points used by Frazer and Pinto to define the "time period" of HPV elicited immune response during which Hodgkin's might arise. Dr. McCabe estimated that increased cytokine production occurred up to seven months following vaccination. Id. (citing exhibit 34 (Frazer); exhibit 35 (Pinto)). However, Dr. McClain persuasively showed that Dr. McCabe misinterpreted the Frazer and Pinto studies such that they did not support Dr. McCabe's assumption regarding increased cytokine production up to seven months following vaccination. Exhibit BB at 2-3.

On the remaining Althen prong, Ms. Shortnacy's evidence is similarly unimpressive. The second Althen prong requires Ms. Shortnacy to establish by preponderant evidence "a logical sequence of cause and effect" showing that the HPV vaccine caused her Hodgkin's. Althen, 418 F.3d at 1274. Factors that can make Ms. Shortnacy's case "logical" include evidence showing that her Hodgkin's arose by the means predicted by her expert's theory and the views of her treating physicians. LaLonde v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1340 (Fed. Cir. 2014) (special master did not err in requiring some proof that petitioner's theory actually explained petitioner's injury) (citing Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012) (petitioner required to show both the likelihood of her theory of causation and that the alleged injury was consistent with that theory)); Moberly, 592 F.3d at 1324-25.

Dr. McCabe suggested that Ms. Shortnacy's previously observed titers for EBV may have played a role in facilitating the HPV vaccination in causing Hodgkin's. Exhibit 13 at 4-5. However, the EBER testing done at Dr. McClain's suggestion showed that no EBV was present in Ms. Shortnacy's biopsy. See

¹² Dr. McCabe has had previous trouble establishing the third prong of Althen. See Koehn, 2013 WL 3214877, at *32; see also Godfrey, 2014 WL 3058353, at *23.

exhibit 42; see also exhibit E at 3; exhibit EE. Ms. Shortnacy has not provided other evidence that the remainder of Dr. McCabe's theory was likely at work in causing her Hodgkin's.

In sum, Ms. Shortnacy has not demonstrated the persuasiveness of Dr. McCabe's opinion regarding any Althen prong. On the simplest level, Dr. McCabe is much, much less knowledgeable about Hodgkin's than Dr. McClain. Ms. Shortnacy has presented no persuasive reason that her expert, who has never studied Hodgkin's, should be credited over the Secretary's expert, who is probably among this country's most knowledgeable doctors on Hodgkin's.

V. Conclusion

Ms. Shortnacy seeks compensation in the Vaccine Program alleging that the HPV vaccines she received caused her Hodgkin's disease. Ms. Shortnacy has failed to demonstrate by a preponderance of the evidence that the onset of her Hodgkin's occurred within the time allowed under the statute of limitations or that her Hodgkin's was caused-in-fact by the HPV vaccines she received. Consequently, she is not entitled to compensation.

The Clerk's Office is instructed to issue judgment in accord with this decision.

IT IS SO ORDERED.

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