In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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DAVID LANDIS,	*	
	*	No. 15-1562V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	Filed: August 20, 2019
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement, Tdap, osteoarthritis, fact ruling
	*	
Respondent.	*	
* *		

Dan Bolton, III, Bolton Law PLLC, Cary, NC, for petitioner;
Jennifer Reynaud, United States Dep't of Justice, Washington, DC, for respondent.

DECISION DENYING COMPENSATION[1]

Before receiving a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine in 2013, David Landis, the petitioner, suffered from many health problems, including osteoarthritis. Osteoarthritis is a noninflammatory degenerative disease of the joints. Mr. Landis alleges that the Tdap vaccine significantly aggravated his osteoarthritis, and the Secretary of Health and Human Services, the respondent, disputes this allegation.

The development of this case took a relatively long time, culminating in a series of reports from experts. Mr. Landis retained Dr. Anna Nowak-Wegrzyn, a pediatrician and allergist/immunologist, whose reports are exhibits 21 and 42. The Secretary retained Dr. Arnold I. Levinson, an internist and allergist/immunologist, whose reports are exhibits A, C, and D.

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. This posting will make the decision available to anyone with the internet. 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.

Mr. Landis has requested a ruling on the record in his favor. Although a resolution based on the papers is appropriate, the record does not support Mr. Landis's claim for entitlement.

I. Procedural History

Mr. Landis began this case by filing a petition on December 21, 2015, which alleged that the Tdap vaccine significantly aggravated his osteoarthritis.[2] The counsel of record who filed the petition and has represented Mr. Landis throughout this litigation is Dan Bolton.[3] Mr. Landis submitted a first set of medical records via compact disc on January 8, 2016. In a March 17, 2016 status conference, Mr. Bolton reported that he was having difficulty getting medical records. See Order, issued Mar. 18, 2016. Mr. Landis filed more medical records via compact disc and a statement of completion on April 29, 2016.

The Secretary filed his report, pursuant to Vaccine Rule 4, on July 29, 2016. Resp't's Rep. The Secretary reviewed Mr. Landis's medical history in considerable detail. Id. at 2-17. Although Mr. Landis had filed a significant number of medical records, the Secretary identified other medical records that were missing and requested their production. Id. at 3-5, 13, 15, 17. With respect to entitlement, the Secretary recommended that compensation be denied because neither a treating doctor nor a retained expert associated the Tdap vaccination with Mr. Landis's osteoarthritis. Id. at 19, 22-23.

In the ensuing status conference, Mr. Bolton agreed to seek the missing medical records. See Order, issued Aug. 11, 2016. Mr. Bolton also requested an opportunity to file a rebuttal to the Secretary's report. Id. On December 18, 2016, Mr. Landis filed one more medical record (see exhibit 15), and on December 28, 2016, he filed his rebuttal to the Rule 4 report.

The parties discussed the state of the record in a January 13, 2017 status conference. Order, issued Jan. 19, 2017. The Secretary continued to request more medical records. Id. Mr. Bolton proposed that for some apparent appointments,

[2] The petition also alleged that the Tdap vaccination caused Mr. Landis's osteoarthritis. However, Mr. Landis's expert did not present a causation-in-fact opinion.

[3] When this decision uses phrases such as "Mr. Landis filed" or "Mr. Landis argued," the participation of Mr. Bolton is implicit. However, in some places, Mr. Bolton's activity is explicit by referring to Mr. Bolton by name.

Mr. Landis did not actually see the medical provider. Id. Mr. Bolton relayed that for some of these visits, Mr. Landis's memory was not sharp. Id.

In the January 13, 2017 status conference, the undersigned also directed Mr. Landis to provide evidence supporting his claim that the worsened osteoarthritis caused him to lose income from his job as a chiropractor. Id. Mr. Landis was instructed to file any W-2s and business tax returns. Id. Finally, Mr. Bolton proposed that the parties should attempt to resolve the case informally. Id.

Mr. Landis filed more medical records on February 5, 2017. Exhibits 16-19. The parties again discussed the status of the record in a status conference on February 15, 2017. Order, issued Feb. 16, 2017. Mr. Bolton relayed that he was having difficulty communicating with Mr. Landis. Id. Mr. Bolton also represented that if the Secretary did not settle the case, then he would retain an expert witness. Id. Mr. Bolton inquired whether the case could be resolved without a hearing. Id. However, the Secretary seemed uninterested in an informal resolution.

With respect to the question of lost earnings, Mr. Bolton had filed Mr. Landis's tax return from 2010 as exhibit 20. Mr. Bolton represented that Mr. Landis had become ill with asthma between 2010 and 2013, a time in which he did not see many patients. Mr. Bolton further stated that Mr. Landis's sister closed his office in August 2014 and destroyed his office records.

To facilitate the process of obtaining useful reports from experts, the undersigned proposed a set of instructions in his February 16, 2017 order. After not receiving any comments, the undersigned made those proposed instructions final. See order, issued Mar. 6, 2017.

On behalf of Mr. Landis, Mr. Bolton filed a status report on April 7, 2017, discussing many issues. In response to the plan to obtain reports from experts, Mr. Bolton relayed that he was retaining an expert. As to the information regarding Mr. Landis's lost earnings, Mr. Bolton stated that 2010 was the most recent year that Mr. Landis submitted a tax return. Finally, Mr. Bolton also reported that he had requested information on the Tdap vaccine and arthritis, together with pre- and post-marketing findings and reports, from GlaxoSmithKline but had not received any response.

Mr. Landis filed a report from Dr. Nowak-Wegrzyn on May 4, 2017. Exhibit 21. As discussed below, Dr. Nowak-Wegrzyn generally opined that the Tdap vaccination significantly aggravated Mr. Landis's osteoarthritis. See id. Mr.

Landis also submitted Dr. Nowak-Wegrzyn's curriculum vitae and the articles she cited in her report. Exhibits 22-41.

The Secretary responded with a report from Dr. Levinson, filed on August 21, 2017. Exhibit A. Dr. Levinson agreed with Dr. Nowak-Wegrzyn that Mr. Landis suffered from osteoarthritis before the Tdap vaccination. See id. However, Dr. Levinson maintained that the Tdap vaccination did not affect Mr. Landis adversely. Id.

Mr. Bolton filed a motion for discovery on September 26, 2017. Mr. Bolton sought further information about Dr. Levinson. Specifically, Mr. Bolton wanted to know how many times Dr. Levinson had testified in medico-legal matters in the previous five years and what percentage of his income was derived from such activity. Mr. Bolton also wanted to ascertain whether Dr. Levinson had any affiliations with GlaxoSmithKline or with any of its affiliates. The September 26, 2017 motion for discovery did not request any information from GlaxoSmithKline. The undersigned eventually ordered Dr. Levinson to provide a limited amount of additional information (see order, issued Oct. 18, 2017), and Dr. Levinson did so on December 8, 2017. Exhibit C.

Meanwhile, Dr. Nowak-Wegrzyn wrote a rebuttal report, which was filed as exhibit 42 on October 29, 2017. With Dr. Nowak-Wegrzyn's rebuttal report on file, Mr. Bolton filed a motion for a ruling on the record on January 6, 2018. The Secretary responded on January 23, 2018.

The undersigned denied the motion for a ruling on the record without prejudice. Order, issued May 1, 2018. The undersigned found that the motion was not adequately developed. Id. The undersigned also allowed the Secretary to file a response to Dr. Nowak-Wegrzyn's most recent report. Id.

The Secretary filed the final expert report from Dr. Levinson on July 13, 2018. Exhibit D. The parties discussed the experts' presentations in an August 20, 2018 status conference. See order, issued Aug. 21, 2018. After learning that openings for hearings on the undersigned's calendar were more than one year away, Mr. Bolton suggested that an appropriate procedure to resolve the case was a motion for a ruling on the record. Id. Mr. Bolton explained that funding the litigation was problematic. Id. In response, the undersigned suggested that Mr. Bolton could file a motion for an award of attorney's fees and costs on an interim basis. Id.

Mr. Bolton did file such a motion on October 26, 2018. In a February 5, 2019 decision, the undersigned awarded Mr. Landis all the attorney's fees and costs that the October 26, 2018 motion requested. 2019 WL 1061516.

On December 11, 2018, Mr. Landis filed the pending motion for a ruling on the record. The Secretary filed his response on March 28, 2019, and Mr. Landis replied on May 28, 2019. With the filing of Mr. Landis's reply, the case is ready for adjudication.[4]

II. Standards for Adjudication

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa–11(c)(2). Medical records that are created contemporaneously with the events they describe are presumed to be accurate. Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Not only are medical records presumed to be accurate, they are also presumed to be complete, in the sense that the medical records present all the patient's medical issues. Completeness is presumed due to a series of propositions. First, when people are ill, they see a medical professional. Second, when ill people see a doctor, they report all of their problems to the doctor. Third, having heard about the symptoms, the doctor records what he or she was told.

Appellate authorities have accepted the reasoning supporting a presumption that medical records created contemporaneously with the events being described are accurate and complete. A notable example is Cucuras in which petitioners asserted that their daughter began having seizures within one day of receiving a vaccination, although medical records created around that time suggested that the

[4] This decision refers to the most relevant pleadings as "Pet'r's Mot.," Resp't's Resp.," and "Pet'r's Reply."

seizures began at least one week after the vaccination. Cucuras, 993 F.3d at 1527. A judge reviewing the special master's decision stated that "[i]n light of [the parents'] concern for [their daughter's] treatment . . . it strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred." Cucuras v. Sec'y of Health & Human Servs., 26 Cl. Ct. 537, 543 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993).

Judges of the Court of Federal Claims have followed Cucuras in affirming findings by special masters that the lack of contemporaneously created medical records can contradict a testimonial assertion that symptoms appeared on a certain date. See, e.g., Doe/70 v. Sec'y of Health & Human Servs., 95 Fed. Cl. 598, 608 (Fed. Cl. 2010) (stating, "[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), aff'd sub nom. Rickett v. Sec'y of Health & Human Servs., 468 Fed. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion); Doe/17 v. Sec'y of Health & Human Servs., 84 Fed. Cl. 691, 711 (2008); Ryman v. Sec'y of Health & Human Servs., 65 Fed. Cl. 35, 41-42 (2005); Snyder v. Sec'y of Health & Human Servs., 36 Fed. Cl. 461, 465 (1996) (stating, "[t]he special master apparently reasoned that, if [the vaccinee] suffered such [developmental] losses immediately following the vaccination, it was more likely than not that this traumatic event, or his parents' mention of it, would have been noted by at least one of the medical record professionals who evaluated [the vaccinee] during his life to date. Finding [the vaccinee's] medical history silent on his loss of developmental milestones, the special master questioned petitioner's memory of the events, not her sincerity."), aff'd, 117 F.3d 545, 547-48 (Fed. Cir. 1997).

The presumption that contemporaneously created medical records are accurate and complete is rebuttable, however. For cases alleging a condition found in the Vaccine Injury Table, special masters may find when a first symptom appeared, despite the lack of a notation in a contemporaneous medical record. 42 U.S.C. § 300aa-13(b)(2). By extension, special masters may engage in similar fact-finding for cases alleging an off-Table injury. In such cases, special masters are expected to consider whether medical records are accurate and complete. To overcome the presumption that written records are accurate, testimony is required to be "consistent, clear, cogent, and compelling." Blutstein v. Sec'y of Health &

Human Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998).

In determining the accuracy and completeness of medical records, special masters will consider various explanations for inconsistencies between contemporaneously created medical records and later given testimony. The Court of Federal Claims has identified four such explanations for explaining inconsistencies: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. La Londe v. Sec'y Health & Human Servs., 110 Fed. Cl. 184, 203 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014).

When weighing divergent pieces of evidence, special masters usually find contemporaneously written medical records to be more significant than oral testimony. Cucuras, 993 F.2d at 1528. Testimony offered after the events in question is less reliable than contemporaneous reports when the motivation for accurate explication of symptoms is more immediate. Reusser v. Sec'y of Health & Human Servs., 28 Fed. Cl. 516, 523 (1993). However, compelling oral testimony may be more persuasive than written records. Campbell ex rel. Campbell v. Sec'y of Health & Human Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."); Camery v. Sec'y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998) (this rule "should not be applied inflexibly, because medical records may be incomplete or inaccurate"); Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991) ("[T]he absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance") (citation omitted), aff'd, 968 F.2d 1226 (Fed. Cir. 1992).

III. Facts[5]

A. Overview of the Parties' Disputes About Facts

The participants differ on events in Mr. Landis's life, particularly before the Tdap vaccination. The Secretary and his expert, Dr. Levinson, sing with one voice—they treat the medical records created contemporaneously with the events being described in the medical records as accurate. Dr. Nowak-Wegrzyn, Mr. Landis's expert, seems to share this view as she states that before the vaccination Mr. Landis suffered from:

> multiple, poorly controlled atopic conditions (eczema, asthma, allergic rhinitis), osteoarthritis, obesity, and poor coping with his multiple health problems as evidenced by suboptimal adherence to the asthma and eczema treatment regimens (noted repeatedly by various medical providers throughout the medical records) and a sickly, disheveled, unkempt appearance, older than his chronological age.

Exhibit 21 at 9. However, Mr. Landis and Mr. Bolton take a different view. Before this vaccination, Mr. Landis's "health was excellent." Pet'r's Mot. at 2, citing exhibit 3 (Mr. Landis's affidavit) at 1; see also exhibit 4 (affidavit of Mr. Landis's personal attorney, Karl Kreiser). As discussed below, the stronger and better evidence is consistent with the position taken by the Secretary and not consistent with the position of Mr. Landis.

Crediting Mr. Landis's version is difficult for several reasons. Most fundamentally, Mr. Landis's account is contrary to the medical records created in the years before he was vaccinated. In addition, in the briefing on the motion for ruling on the record, Mr. Landis generally failed to rebut the Secretary's assertions of fact. Finally, Mr. Landis's accounts have been inconsistent.

An example of erratic recounting concerns Mr. Landis's employment status. Some inconsistencies appear within medical records. On May 19, 2012, Mr. Landis's primary care physician recorded that "Mr. Landis used to work as a

[5] In general, the Secretary's recitation of events is chronologically organized and tracks well the underlying medical records. See Resp't's Rep. at 2-17. In contrast, Mr. Landis's presentation is not as well organized. See Pet'r's Rebuttal, filed Dec. 28, 2016; Pet'r's Mot. at 2.

chiropractor." Exhibit 14 at 38. On the other hand, medical records from 2013 refer to him as still working. See id. at 76; exhibit 17 at 18.

Other inconsistencies come from Mr. Bolton. In the petition, Mr. Landis asserted that he was actively employed. Pet., filed Dec. 21, 2015, at ¶ 3. Yet, two years later, Mr. Bolton wrote, "Petitioner closed his chiropractic office about Aug[.] 2014 because of his disabilities related to the Tdap vaccine." Pet'r's Rebuttal, filed Dec. 28, 2016, at 4 (referencing footnote 1). In the February 15, 2017 status conference, Mr. Bolton stated that Mr. Landis's sister closed his practice in August 2014.

Another level of confusion comes from records government agencies kept from information Mr. Landis supplied. After being directed to submit his tax returns (see order, issued Jan. 19, 2017), Mr. Landis represented that "[f]or the past 3 years, [he] did not file federal or state taxes (since his income was below minimum for filing) and has not since 2010. 2010 tax records are included. See exhibit 19." Pet'r's Status Rep., filed Feb. 5, 2017.[6] However, the Commonwealth of Pennsylvania reports that Mr. Landis renewed his license to practice as a chiropractor on August 29, 2014. Court exhibit 1002.

Collectively, this evidence suggests that Mr. Landis (as well as Mr. Bolton as Mr. Landis's agent) cannot provide a consistent and accurate information in response to a basic inquiry—was Mr. Landis working? Although Mr. Landis's employment status sheds indirect light on his health, the more general point is that Mr. Landis has not presented consistent and credible accounts about his employment. Thus, he seems unlikely to provide accurate assertions on more difficult questions such as the state of his health years earlier. For these reasons, in finding the following facts, the undersigned relies upon information contained in medical records created contemporaneously with the events being described in the medical records.

B. Health Before Vaccination

The earliest medical record appears to come from an internist, Jennifer P. Goldstein, in 2009, approximately 3 ½ years before the relevant Tdap vaccination. See exhibit 14. At that visit, Mr. Landis was seeking medical assistance for his chronic obstructive pulmonary disease ("COPD")/asthma. Id. at 1. Dr. Goldstein

[6] Exhibit 19 is Mr. Landis's 2010 tax return, prepared on a 1040 form. The preparer was Richard R Killian, CPA. Mr. Killian has dated the tax return as January 28, 2017. Mr. Landis has not submitted any explanation for why his 2010 tax return is dated seven years later.

observed that Mr. Landis had a "chronic rash all over the skin that [was] pruritic in nature." Id. Dr. Goldstein described Mr. Landis as "pleasant but somewhat unkempt." Id.[7]

Three features that Dr. Goldstein noted in 2009 appear frequently in the medical records before the vaccination. Mr. Landis required assistance for COPD or asthma. Mr. Landis suffered skin problems. And, Mr. Landis's appearance was unkempt. Details can be found in the Secretary's response to the petitioner's motion for a ruling on the record. See, e.g., Resp't's Resp. at 2-11.

In 2012, which was the year before the relevant vaccination, Mr. Landis saw medical personnel at least 11 times. Some of these visits were for asthma and/or a skin problem and seem not directly relevant to Mr. Landis's osteoarthritis. However, a few medical records from 2012 stand out:

- Dr. Goldstein stated, "I believe there is a large psychiatric component with this patient." Exhibit 14 at 36 (March 27, 2012).
- An April 11, 2012 chest x-ray showed "degenerative changes of the spine." Exhibit 15 at 159.
- Mark DeCaro, an internist, described Mr. Landis as "an elderly man." Exhibit 14 at 39 (May 19, 2012). Dr. DeCaro recorded that Mr. Landis "bends at the waist when he stands, secondary to stiffness." Id.
- Ryan R. Gaffney, a Doctor of Osteopathic Medicine, described Mr. Landis as a "65-year-old gentleman, [who] appears much older than his stated age." Id. at 47-48. Dr. Gaffney stated that Mr. Landis was "sitting slumped in the chair secondary to some generalized weakness in his back and legs." Id.

Medical personnel recorded similar comments in records created during the first four months of 2013, during which Mr. Landis had at least five encounters with medical personnel. Significant notations include:

- Shaheb Abbasi, an internist, described Mr. Landis as an elderly man, who "seem[ed] uncomfortable due to generalized pruritis." Id. at 67-68 (January 17, 2013).

[7] Dr. Goldstein recorded that a dermatologist was treating Mr. Landis for psoriasis. Exhibit 14 at 1. Mr. Landis did not file any records from a dermatologist reflecting care in 2009. This omission is just one of many places where the medical records refer to treatment for which a record was not filed.

- Zachary Jensen, an internist, described Mr. Landis as "a fairly frail-appearing middle-aged man appearing much older than his stated age of 66 years." Id. at 69.

These records are the background for Mr. Landis's appointment with Dr. Henock M. Ayalew, an internist, on May 2, 2013. Dr. Ayalew described Mr. Landis as "a disheveled male, frail-appearing, he has poor hygiene and he is wearing clothing that appears to be of poor hygiene as well, he is in mild discomfort from pruritus and he is itching all over his body." Exhibit 14 at 71. Dr. Ayalew encouraged Mr. Landis to follow up with his dermatologists and to take the medicines that the doctors were prescribing. Id. at 72. In addition, Dr. Ayalew wrote: "It appears that he has not received a tetanus shot and there is nothing indicating past immunization over the last 5 years, so I will give him a tetanus shot here in the clinic today."[8] Id. Mr. Landis receive the Tdap vaccine in his right deltoid. Exhibit 2; exhibit 14 at 72.

C. Health After Vaccination

Following the May 2, 2013 vaccination, Mr. Landis next saw a medical practitioner on June 3, 2013. Nurse Practitioner Stephanie A. Mnich evaluated Mr. Landis's right ankle and calf, which had open ulcerations. Exhibit 15 at 149, 151. Ms. Mnich stated: "Secondary to his disheveled appearance as well as overgrowth of his toenails, I did send a consultation note over to our foot and ankle department for podiatry consult for nails." Id. at 152.

According to an affidavit that Mr. Landis submitted in this litigation, within two weeks of his vaccination, he started to experience pain in his lower back and hip. Exhibit 3 at ¶ 4; see also Pet'r's Mot. at 4 ¶ iv.a. Mr. Landis argues that

[8] Mr. Landis emphasizes that he did not consent to the vaccination. Pet'r's Mot. at 9; Pet'r's Reply at 3; exhibit 3 (affidavit). However, in the Vaccine Program, consent or the lack thereof is not relevant. See Bloch v. Sec'y of Dep't of Health & Human Servs., 126 Fed. Cl. 460, 467 (2016) (finding that the special master did not abuse his discretion by dismissing the petition without first ordering production of hospital records that would show the parents had not consented to their child's vaccination, because '"the question of 'consent' to a vaccination seems irrelevant, since under the Vaccine Act, causation is the only issue—the 'fault' of any health provider is never an issue"')

medical records do not memorialize this pain because he was not seeking treatment from an allopathic doctor due to his training as a chiropractor. Pet'r's Mot. at 22.

The undersigned declines to credit this assertion. As discussed in the recitation of events before vaccination, Mr. Landis often sought treatment from allopathic doctors. In addition, if Mr. Landis were truly experiencing hip and back pain by May 17, 2013, he could have easily told Nurse Practitioner Mnich when he saw her on June 3, 2013.

The omission of any complaint about hip or back pain in the record from June 3, 2013, is consistent with the omission of any similar complaint in the next medical appointment, which occurred on July 11, 2013. Then, Mr. Landis saw Dr. Ayalew for his dermatitis. Dr. Ayalew described Mr. Landis as a "disheveled male, [with] very poor hygiene [and] hunched over when walking." Exhibit 14 at 78-79. Although Mr. Landis was requesting IV antibiotics to relieve a perceived systemic infection, Dr. Ayalew recommended that Mr. Landis bathe himself daily and take the prescribed medications. Id.

Mr. Landis argues that the July 11, 2013 visit with Dr. Ayalew supports his claim that he was experiencing hip and back pain shortly after the vaccination. See Pet'r's Mot. at 8; see also exhibit 21 (Dr. Nowak-Wegrzyn's report) at 10. Specifically, Mr. Landis focuses on the notation that he was "hunched over when walking." But, as the Secretary points out (see Resp't's Resp. at 23-24), Dr. Ayalew's July 11, 2013 note is similar to Dr. Ayalew's report on May 2, 2013.

About two months later (or slightly more than four months after the vaccination), the evidence that Mr. Landis's condition had deteriorated is more persuasive. On September 16, 2013, Mr. Landis returned to see Dr. Ayalew in a follow-up visit. Mr. Landis's sister from California accompanied Mr. Landis on this visit. Dr. Ayalew recorded that Mr. Landis's sister was "very concerned about his functional status" because, in part, he seemed to be "hoarding a lot of material at home." Exhibit 14 at 76. Dr. Ayalew also wrote that Mr. Landis was working, but he was "unable to provide adequate care as a therapist." Id. Dr. Ayalew again described Mr. Landis as a "disheveled male, hunched over when he is ambulating." Id. In contrast to previous reports, Dr. Ayalew added that Mr. Landis "continue[d] to walk with a walker." Id. Mr. Landis's use of a walker suggests that he was having more difficulties. Dr. Ayalew referred Mr. Landis to a social worker to address his functional status, see id. at 77, but records from any evaluation from a social worker are not readily apparent within the filed exhibits.

In 2014, Mr. Landis continued to see doctors for asthma and skin problems. Some records include complaints potentially related to Mr. Landis's (undiagnosed) osteoarthritis. For example, on January 15, 2014, Mr. Landis told Bret A. Daniels, a family medicine doctor, that he has been having "ongoing back and upper thigh discomfort and gait disturbance for 1 year."[9] Exhibit 18 at 28. Dr. Daniels recorded that Mr. Landis was "unable to stand straight" and his walking position was "flexed forward." Id. at 30. In response, Dr. Daniels referred Mr. Landis to Orthopedic Associates of Lancaster, but Mr. Landis did not follow up on this referral. Id. at 31.

Dr. Daniels made other referrals to an orthopedist as well, most of which Mr. Landis declined. See id. at 33 (March 18, 2014), 77 (July 17, 2014), 104 (October 1, 2014). In these intervening appointments, Dr. Daniels noted that Mr. Landis walked with a bent-over stance. See, e.g., id. at 88 (August 28, 2014).

Eventually, on referral from Dr. Daniels, an orthopedic surgeon, David Hughes, saw Mr. Landis on October 3, 2014. See exhibit 5(a) at 1-2. Mr. Landis complained about lower back pain, weakness in his quadriceps, and an inability to stand straight. Id. at 1. Mr. Landis reported that his back pain and leg weakness began a year earlier.[10] Id. After Dr. Hughes examined Mr. Landis, Dr. Hughes recorded that Mr. Landis walked with his trunk flexed forward 60 degrees and he had significantly decreased rotation in both hips. Id. at 2. X-rays showed that Mr. Landis's hips had degenerative changes and they also showed degeneration in Mr. Landis's lumbar and thoracic spine. Id. Dr. Hughes's list of potential diagnoses included degenerative arthritis. Id.

Dr. Hughes's October 3, 2014 report carries significance in this case because both Dr. Nowak-Wegrzyn and Dr. Levinson see it as presenting objective signs of Mr. Landis's osteoarthritis. See exhibit 42 at 3; exhibit A at 5-6. Given this agreement that Mr. Landis was displaying signs of osteoarthritis no later than October 3, 2014, the series of medical records created after this date are relatively less relevant to determining whether the May 2, 2013 Tdap vaccination caused Mr.

[9] If this report were accurate, then Mr. Landis's problem with back pain started in January 2013, which is before the May 2, 2013 vaccination.

[10] This chronology is different from the history that Mr. Landis provided to Dr. Daniels in January 2014. See exhibit 18 at 28. If the history given to Dr. Hughes were accurate, then Mr. Landis's back pain started in October 2013, which is about five months after the May 2, 2013 vaccination.

Landis's osteoarthritis to worsen. See Pet'r's Mot. at 9 (ending recitation of facts with a medical record dated November 6, 2014).

Among the more recent medical records, the most relevant reflects a discussion between Mr. Landis and Charles Prezzia, an internist, on November 6, 2014. Mr. Landis sought medical attention because he had "watched an internet video of a doctor who warned of the risk of immunization and he [Mr. Landis] believe[d] that the Tdap shot caused the leg weakness and back pain since 2013." Exhibit 14 at 82. Dr. Prezzia also wrote that Mr. Landis was "only [t]here to address the fact that he felt that the adverse reaction to the vaccination should be reported." Id. Upon examination, Dr. Prezzia determined that Mr. Landis's "muscle strength in his hips, both on flexion [and] extension was normal when he was sitting on both sides, further indicating that the feeling of weakness [was] likely secondary to chronic pain from ongoing poor posture." Id. at 83. Dr. Prezzia informed Mr. Landis that "the likelihood of a Tdap shot causing muscle weakness or pain for as long as 18 months after receiving a shot would be highly unlikely to the point where it is not even listed on the rare side effects." Id. Dr. Prezzia's November 6, 2014 report appears to be the only instance in which a doctor documented some opinion regarding a potential adverse effect of the May 2, 2013 Tdap vaccination. See Pet'r's Mot. at 22-23 (failing to note any treating doctors who offered opinions supporting a logical sequence of cause-and-effect between the vaccination and the worsening of Mr. Landis's osteoarthritis). Remaining medical records primarily concern treatment for osteoarthritis (and other conditions) without necessarily discussing the etiology of the osteoarthritis.

IV. Analysis

Mr. Landis is claiming that the Tdap vaccination significantly aggravated his pre-existing osteoarthritis. As such, the elements of his case are set forth in Loving. Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135 (2009); see also W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that the Loving test "provides the correct framework for evaluating off-table significant aggravation claims"). Loving sets out six elements that a petitioner must prove:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory

> causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144. These are reviewed below.

A. Condition Before Vaccination

Before the Tdap vaccination, X-rays revealed degenerative changes in Mr. Landis's spine. See exhibit 14 at 52 (October 18, 2012); exhibit 15 at 159 (April 11, 2012). Mr. Landis does not challenge this finding. See Pet'r's Mot. at 13 (acknowledging radiographic evidence for his osteoarthritis).

In addition to this radiographic evidence, Mr. Landis displayed some impaired movements. See exhibit 14 at 38 (medical record from May 19, 2012, noting that Mr. Landis associated stiffness with his use of prednisone), 47-48 (medical record from July 2, 2012).

Besides osteoarthritis, Mr. Landis suffered from other problems before the vaccination. These pre-existing problems included asthma and various skin problems, although the extent to which they contributed (if at all) to Mr. Landis's joint problems after vaccination is not entirely clear.

B. Condition After Vaccination

As noted in the fact section above, by September 16, 2013, Mr. Landis was using a walker. (The medical record does not state when he began using a walker.) Mr. Landis's use of a walker constitutes a change in his condition.

The extent and duration of this decreased mobility is not clear. On January 15, 2014, Mr. Landis saw Dr. Daniels, who commented that Mr. Landis walked in a "flexed forward" position. Exhibit 18 at 30. Dr. Daniels, however, did not explicitly note that Mr. Landis was using a walker.

Evidence that Mr. Landis was still using a walker comes from a March 15, 2014 medical record. Exhibit 17 at 15. But, whether Mr. Landis continued to use a walker remains uncertain as Dr. Hughes on October 3, 2014, also did not document the use of a walker. See exhibit 5(a) at 1-2. Finally, during a physical

therapy session on January 9, 2015, Mr. Landis explicitly declined the need for a walker. Exhibit 7 (a) at 7; exhibit 18 at 362 (duplicate).[11]

C. Significant Aggravation

Congress defined significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4). The parties' briefs on this point are relatively conclusory. See Pet'r's Mot. at 9, Resp't's Resp. at 24, Pet'r's Reply at 4.

Due to the sparseness of information, a factual finding on this point is difficult to make. As discussed above, the evidence about Mr. Landis's employment varied. He also suffered from other problems and this multiplicity of diseases makes an analysis of his osteoarthritis more challenging. Ultimately, the undersigned will assume, for the sake of argument, that Mr. Landis established preponderant evidence that his osteoarthritis was markedly worse sometime after the vaccination.

D. Medical Theory Causally Connecting Vaccination and Injury

Here, through Dr. Nowak-Wegrzyn, Mr. Landis advances the theory that the adjuvant in the Tdap vaccination induced an activation of his innate immune system. See Pet'r's Mot. at 9-11; exhibit 42 (Dr. Nowak-Wegrzyn's report at 6).[12] In the context of this case, this theory is not persuasive.

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[11] Mr. Bolton recognizes that Mr. Landis's condition improved but argues that the improvement may have been because Mr. Landis was living in better housing. Pet'r's Reply at 2. Mr. Landis did not submit any affidavits that discuss his living situation.

[12] The Secretary asserts that Dr. Nowak-Wegrzyn has propounded a theory Dr. Shoenfeld first advanced, known as Autoimmune Syndrome Induced by Adjuvant ("ASIA"). Resp't's Resp. at 25. As evidence, the Secretary points out that Dr. Nowak-Wegrzyn cited articles Dr. Shoenfeld or his colleagues wrote. See exhibits 23, 25-30, 32. Mr. Landis did not address this point directly, neither agreeing with the assertion that his expert was advancing the ASIA theory nor disagreeing with this assertion. See Pet'r's Reply.

The difference between Dr. Nowak-Wegrzyn's theory here and ASIA is not readily apparent. Nevertheless, the undersigned assumes that there is some distinction. However, if Dr. Nowak-Wegrzyn were simply asserting ASIA, then her opinion would not be persuasive due to a strong line of cases declining to credit ASIA. See D'Angiolini v. Sec'y of Health & Human Servs., 122 Fed. Cl. 86, 102 (2015) (upholding special master's "determin[ation] that ASIA does not provide[] a biologically plausible theory for recovery"), aff'd, 645 Fed. Appx. 1002 (Fed. Cir. 2016); Garner v. Sec'y of Health & Human Servs., No. 15–063V, 2017 WL 1713184, at *8

Mr. Landis recognizes that no studies have affirmatively linked the Tdap vaccination and osteoarthritis. Pet'r's Mot. at 10.[13] Although literature is not required, Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1279-80 (Fed. Cir. 2005), "a scientific theory that lacks any empirical support will have limited persuasive force." Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 134 (2011), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012).[14] When the Institute of Medicine ("IOM") examined this question, it found that the evidence was insufficient to accept or to reject a causal relationship. Court exhibit 1001 at 571.

(Fed. Cl. Spec. Mstr. Mar. 24, 2017) (observing that the ASIA theory "is, at a minimum, incomplete and preliminary—and therefore unreliable from an evidentiary standpoint"); Johnson v. Sec'y of Health & Human Servs., No. 10–578V, 2016 WL 4917548, at *7–9 (Fed. Cl. Spec. Mstr. Aug. 18, 2016) (rejecting Dr. Shoenfeld's expansive medical theory that "any adjuvant [is] capable of causing any autoimmune disease," finding it "overbroad, generalized, and vague, to the point that it could apply to virtually everyone in the world who received a vaccine containing an adjuvant and then at some time in their lives developed an autoimmune disease"); Rowan v. Sec'y of Health & Human Servs., No. 10–272V, 2014 WL 7465661, at *12 (Fed. Cl. Spec. Mstr. Dec. 8, 2014) (rejecting the ASIA theory because it "is not a proven theory" and no "persuasive or reliable evidence" supports it).

[13] Somewhat inconsistently, Mr. Landis argues that the manufacturer's package insert supports the causal relationship between Boostrix (the Tdap vaccine in question marketed by GlaxoSmithKline) and osteoarthritis. See Pet'r's Mot. at 13, relying upon exhibit D, tab 4. But, a manufacturer's recitation that one event (osteoarthritis) followed an earlier event (vaccination with Tdap) is not a statement of causality. See Bender v. Sec'y of Health & Human Servs., No. 11-693V, 2018 WL 3679637, at *31 (Fed. Cl. Spec. Mstr. Jul. 2, 2018) (noting that "vaccine package inserts do not constitute causation evidence meriting significant weight"), mot. for rev. denied, 141 Fed. Cl. 262 (2019); see also Werderitsh v. Sec'y of Health & Human Servs., No. 99–319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (quoting 21 C.F.R. § 600.80(l) as stating that "[a] report or information submitted by a licensed manufacturer . . . does not necessarily reflect a conclusion by the licensed manufacturer or FDA that the report or information constitutes an admission that the biological product caused or contributed to an adverse effect").

[14] The Federal Circuit has also stated: "In Vaccine Act cases, petitioners must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation under the preponderance of the evidence standard. The level of specificity of such support may vary from circumstance to circumstance." LaLonde v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1341 (Fed. Cir. 2014). Here, consistent with Althen, the undersigned is not requiring the petitioner to produce medical literature as a matter of law. The undersigned is simply pointing out that the lack of support from studies makes the expert's theory less persuasive.

In lieu of studies on Tdap vaccine and osteoarthritis, Dr. Nowak-Wegrzyn relies upon articles about different conditions, such as ASIA or rheumatoid arthritis. See exhibit 21 at 7-8. But, Dr. Nowak-Wegrzyn does not explain why the pathogenesis of different conditions would inform whether Tdap vaccine can cause osteoarthritis. Such explanation would have been helpful here because osteoarthritis is not considered to be an autoimmune disease. See exhibit 42 at 4 (Dr. Nowak-Wegrzyn wrote: "I agree with my esteemed colleague [Dr. Levinson] that [osteoarthritis] is not an autoimmune disease, and I have not made that claim anywhere in my opinion"). So, too, Mr. Landis's reliance on cases, such as Means v. Sec'y of Health & Human Servs., No. 12-740V, 2015 WL 6689236 (Fed. Cl. Oct. 13, 2015), in which the injury was not osteoarthritis, or another non-autoimmune disease, is misplaced. See Pet'r's Mot. at 18, 20, Pet'r's Reply at 4-5.

Fundamentally, Dr. Nowak-Wegrzyn is positing that the Tdap vaccination causes an increase in cytokines and an increase in cytokines causes disease. Special masters have found cytokine-based theories not persuasive. Zumwalt on behalf of L.Z. v. Sec'y of Health & Human Servs., No. 16-994V, 2019 WL 1953739, at *18 (Fed. Cl. Spec. Mstr. Mar. 21, 2019) (noting that "[t]he fact that vaccines are known to stimulate cytokine production . . . does not amount to a reliable causation theory that such stimulation is necessarily disease-causing"); Inamdar v. Sec'y of Health & Human Servs., No. No. 15-1173V, 2019 WL 1160341, at *17 (Fed. Cl. Spec. Mstr. Feb. 8, 2019) (noting that the proposition that vaccines can cause diseases by "induc[ing] the production of proinflammatory cytokines . . . has several deficiencies"); McCabe v. Sec'y of Health & Human Servs., No. 13-570V, 2018 WL 3029175, at *47-55 (Fed. Cl. Spec. Mstr. May 17, 2018); McGuire v. Sec'y of Health & Human Servs., No. No. 10-609V, 2015 WL 6150598 at *12-18 (Fed. Cl. Spec. Mstr. Sep. 18, 2015) (noting that the petitioner had failed to introduce "persuasive evidence to rebut the IOM's conclusion that no evidence supports a conclusion that cytokines cause a disease").

For these reasons, Mr. Landis has not met his burden of presenting a persuasive medical theory causally connecting the Tdap vaccination and the worsening of his osteoarthritis.

E. Timing[15]

The timing prong actually contains two parts. A petitioner must show the "timeframe for which it is medically acceptable to infer causation" and that the onset of the disease occurred in this period. Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542-43 (2011), recons. denied after remand on other grounds, 105 Fed. Cl. 353 (2012), aff'd without op., 503 F. App'x 952 (Fed. Cir. 2013).

As to the interval between the vaccination and the worsening of osteoarthritis, Mr. Landis does not really propose any expected duration. See Pet'r's Mot. at 23-24; Pet'r's Reply at 11-12. In her reports, Dr. Nowak-Wegrzyn asserts that the latency period "ranges between days to years." Exhibit 21 at 9; accord exhibit 42 at 3. However, extending a range out to "years" effectively opens the timing window so wide that the criterion becomes empty. See Hennessey v. Sec'y of Health & Human Servs., 91 Fed. Cl. 126, 142 (2010) (the expert's "overly broad" opinion on timing effectively "renders Althen's third prong a nullity").

As to when Mr. Landis experienced a worsening of his osteoarthritis, Mr. Landis and Dr. Nowak-Wegrzyn appear to disagree. Mr. Landis asserts that his "osteoarthritis became severe within two weeks of vaccination." Pet'r's Mot. at 23. In contrast, Dr. Nowak-Wegrzyn opined that the first evidence of a worsened osteoarthritis was on July 11, 2013, 2 ½ months after the vaccination. Exhibit 21 at 10.

Neither of these attributions is persuasive. As explained above, the better and more persuasive evidence from the medical records supports a finding that Mr. Landis's osteoarthritis became worse between July 11, 2013 and September 16, 2013. Because Dr. Nowak-Wegrzyn has relied upon assertions that are not supported by preponderant evidence, her opinion may be discounted. See Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1376 n.6 (Fed. Cir. 1993) ("An expert opinion is no better than the soundness of the reasons supporting it"); Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) ("The special master concluded that the expert based his opinion on facts not substantiated by the record. As a result, the special master properly rejected the testimony of petitioner's medical expert").

[15] Although timing is the sixth Loving element, the analysis in this case flows more logically by addressing timing before the logical sequence of cause and effect element.

Furthermore, special masters have found that if cytokines were to harm the recipient of a vaccine, then the damage would be apparent in a matter of a few days. This relatively short interval follows from the fact that cytokines exist for a matter of hours or days. See, e.g., Reichert v. Sec'y of Health & Human Servs., No. No. 16-697V, 2018 WL 4496561, at *16 (Fed. Cl. Spec. Mstr. Aug. 2, 2018). Thus, even if Mr. Landis's osteoarthritis did worsen by July 11, 2013 (as Dr. Nowak-Wegrzyn asserts), the lapse of time would be too long to be linked to a theory based upon cytokines.

Thus, Mr. Landis has not established the timing prong.

F. Logical Sequence of Cause and Effect

Given that Mr. Landis has established neither a theory nor appropriate timing, it follows as a matter of logic that he cannot establish a logical sequence of cause and effect, linking the Tdap vaccination to his osteoarthritis. See Caves, 100 Fed. Cl. at 145. Nevertheless, for sake of completeness, this criterion is also considered.

With respect to this prong, the Federal Circuit has instructed special masters to consider carefully the views of a treating doctor. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). Mr. Landis has not identified any treating doctor who associated the worsening of his osteoarthritis with the Tdap vaccination. See Pet'r's Mot. at 22; Pet'r's Reply at 11-12. The undersigned also has not independently located any treating doctor who supports Mr. Landis's claim.[16]

On the other hand, the Secretary identified one doctor who proposed an alternative explanation. Resp't's Resp. at 32. Dr. Prezzia stated:

> I told [Mr. Landis] that I suspect that the feeling of leg weakness and pain is likely secondary to his poor gait as he is chronically bent over and his paraspinal muscles are very taut. . . . I also pointed out to him that his muscle strength in his hips, both on flexion [and] extension was normal when he was sitting on both sides, further

[16] Mr. Landis's expression of his belief that the vaccine affected him adversely seems to have begun in 2014, after he watched a video on the Internet. See, e.g., exhibit 14 at 82; exhibit 9 at 4, exhibit 3 (affidavit).

> indicating that the feeling of weakness is likely secondary to chronic pain from ongoing poor posture.

Exhibit 14 at 83 (record from November 6, 2014). In this context, Dr. Prezzia also explicitly addressed and rejected Mr. Landis's suggestion that the Tdap vaccination was causing his problem. Dr. Prezzia wrote, "the likelihood of a Tdap shot causing muscle weakness or pain for as long as 18 months after receiving a shot would be highly unlikely." Id.

Thus, the records from Mr. Landis's treating doctors do not weigh in favor of a finding that the Tdap vaccination affected Mr. Landis adversely.

V. Conclusion

Mr. Landis may genuinely believe that the Tdap vaccination harmed him. However, preponderant evidence in the form of medical records or medical opinions do not support his claim. The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed.[17]

IT IS SO ORDERED.

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

[17] Entry of judgment can be expedited by each party's filing of a notice renouncing the right to seek review. Vaccine Rule 11(a).