IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

FRANCES CAMPBELL,	*	
	*	No. 07-465V
Petitioner,	*	Special Master Christian J. Moran
	*	
v.	*	Filed: July 7, 2009
	*	
SECRETARY OF HEALTH	*	entitlement, flu vaccine, rheumatoid
AND HUMAN SERVICES,	*	arthritis
	*	
Respondent.	*	

Michael Andrew London & Randolph Janis, Douglass and London, P.C., New York, N.Y., for petitioner;
Lisa A. Watts, United States Dep't of Justice, Washington, D.C., for respondent.

PUBLISHED DECISION DENYING COMPENSATION[*]

Frances Campbell alleges that the trivalent influenza vaccine caused her to suffer rheumatoid arthritis. She seeks compensation pursuant to the National Vaccine Injury Program, 42 U.S.C. § 300aa–10 et seq. (2006).

Ms. Campbell has failed to establish the elements required for her to be awarded compensation. Ms. Campbell has not established that the theories offered by her expert are reliable. In addition, Ms. Campbell has not established that even if her expert's theories were

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[*] Because this published decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

All decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, a party has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access. 42 U.S.C. § 300aa–12(d)(4); Vaccine Rule 18(b).

reliable, she experienced signs and symptoms of rheumatoid arthritis within the time predicted by her expert. Therefore, the Clerk's Office is instructed to enter judgment for respondent in accord with this decision.

I. Facts

The relevant facts are not disputed. The parties agree that the medical records submitted as exhibits accurately describe Ms. Campbell's condition. The experts agree that Ms. Campbell suffers from rheumatoid arthritis. Exhibit 10 at 5; exhibit A at 6. However, they disagree about when the rheumatoid arthritis began. Compare tr. 118 (Dr. Brawer stating that the rheumatoid arthritis began on December 6, 2003) with tr. 242 (Dr. Lightfoot stating that he does not know when it began).

A. Before February 2004

Ms. Campbell was born in August 1957. The medical history of her family includes a maternal great-grandmother and great-grandfather who had rheumatoid arthritis. Exhibit 3 at 300025.

Before Ms. Campbell received the flu vaccine, she had some medical problems. For purposes of determining whether the flu vaccine caused her rheumatoid arthritis, the most relevant conditions that existed before Ms. Campbell was vaccinated are bilateral rotator cuff disease and degenerative joint disease in her spine. See exhibits 1 at 100027 (office visit dated Aug. 1, 2003, stating that Ms. Campbell "is having increasing pain in her [right] shoulder. . . . This has been a chronic and recurrent problem for her."); exhibit 1 at 100001, exhibit 1 at 100003 (Ms. Campbell complains of tingling sensation in her shoulder for many years since shoulder surgery), exhibit 1 at 100005 (reference to "multiple shoulder surgeries"), exhibit 1 at 100013 (chronic bilateral shoulder pain). Ms. Campbell reported that she had been disabled since approximately 1999, due to discomfort in her shoulders. Exhibit 3 at 300025 (report dated Dec. 13, 2003).

On Thursday, December 4, 2003, Ms. Campbell saw her primary care doctor, Dr. Thad Jackson. Ms. Campbell complained, among other things, about pain in both shoulders, and depression. Dr. Jackson recommended psychological counseling, which Ms. Jackson declined, and aqua therapy. Exhibit 1 at 100024-25.

During this same visit, Ms. Campbell received the flu vaccine. She also received the pneumococcal vaccine. Id.; exhibit 6. Ms. Campbell received the adult form of the pneumococcal vaccine, which is not listed on the Vaccine Injury Table. See 42 C.F.R. § 100.3(a)(XIII); 66 Fed. Reg. 28166, 28166.

Ms. Campbell returned to Dr. Jackson's office on Monday, December 8, 2003. She reported that she had been feeling as usual until Sunday (the previous day). On Sunday, she

started having pain in her left arm that radiated up to her left shoulder. A few hours later, she developed pain in her right arm. Dr. Jackson examined her, including her upper extremities. Dr. Jackson found that Ms. Campbell's upper arms had systemic swelling and that she had diminished grip strength. Dr. Jackson admitted her to Mercy Hospital. Exhibit 2 at 20100-104.

Ms. Campbell's admission to the hospital produced much information that is relevant to her claim in this case. While in the hospital, Ms. Campbell had an MRI of her brain and an MRI of her cervical spine. The MRI of Ms. Campbell's brain was normal. The MRI of her cervical spine showed some disc bulging at C4/5 and C5/6. Exhibit 2 at 200112-13. X-rays of her lumbosacral spine showed some narrowing of disc space. Id. at 200114. Ms. Campbell tested positive for antinuclear antibodies (ANA). Exhibit 2 at 200093. However, a positive ANA is not necessarily diagnostic for rheumatoid arthritis. Exhibit A at 5, tr. 243-44. Ms. Campbell also experienced extreme pain, although the pain decreased during her stay. Exhibit 12 (Frances Campbell affidavit, dated August 29, 2007) ¶ 3; exhibit 2 at 200093-94.

Ms. Campbell was also seen in the hospital by an orthopedist, Dr. Darius Divina. Dr. Divina could not determine the cause of Ms. Campbell's shoulder pain, numbness or tingling. Exhibit 2 at 200109-11.

Ms. Campbell stayed in Mercy Hospital for two days. When she was discharged, her diagnosis was "[a]cute bilateral upper extremity inflammatory arthritis." Exhibit 2 at 200092. The cause of this condition was not given.

On December 12, 2003, Ms. Campbell visited the emergency room because she was complaining of pain in her extremities, including her left foot. The emergency room doctor stated that he suspected her upper extremity pain was due to inflammatory arthritis. However, neither the doctor's typed report nor his notes of this examination indicate whether Ms. Campbell had swelling in her joints. The emergency room doctor did not admit Ms. Campbell to the hospital, although he arranged a wheelchair for her. Exhibit 2 at 200150-52.

About one week later, Ms. Campbell saw her treating physician, Dr. Jackson, again. She was using the wheelchair to move around her house. Exhibit 3 at 300024. She reported that she had developed weakness in her legs such that she could stand for only ten seconds and could not walk. Exhibit 1 at 100023. But, Ms. Campbell reported that her "joint symptoms, particularly the upper extremities, are 100% better." Exhibit 3 at 300024. Dr. Jackson's examination did not note any swelling in her joints, although Dr. Jackson did note that Ms. Campbell had "some joint tenderness." Exhibit 1 at 100023.

Dr. Jackson's impressions included the following:

> 1 . . . .a constellation of symptoms involving polyarticular arthralgias, myalgias, and new onset of lower extremity weakness in which she is able to stand in the office for only

about 10 seconds before her legs get weak to the point that she has to sit down.

2. Positive RA and ANA profiles, which may represent new rheumatologic disease versus possible reactivity due to her previous influenza vaccine.

Id. at 100022.

On December 19, 2003, Dr. Jackson admitted Ms. Campbell to Grayling Mercy Hospital and Munson Medical Center for evaluation by neurologists and rheumatologists.

Upon admission to Munson Medical Center, Ms. Campbell saw doctors with different specialties. Neuromuscular testing was essentially normal. See exhibit 3 at 300014.

The most important doctor that Ms. Campbell saw was Dr. Gilhooly, a rheumatologist. Dr. Gilhooly reported that she was consulted because there were "[p]ositive serologies, polyarthritis and weakness in a woman status post influenza and Pneumovax vaccinations." Exhibit 3 at 300021. Dr. Gilhooly obtained Ms. Campbell's medical history. Dr. Gilhooly also examined Ms. Campbell. Dr. Gilhooly's findings included: "Musculoskeletal demonstrated tenderness along the MCPs and PIPs to fist formation and grip strength. She had tenderness at the extremes of hip, knee and ankle range of motion. No synovitis was appreciated on examination." Exhibit 3 at 300025.

Dr. Gilhooly's impressions are very important because she was the first doctor specializing in a relevant field to see Ms. Campbell after the vaccination. Dr. Gilhooly's impressions included:

1. Post vaccination reactive arthritis. question myalgias weakness in a woman with positive serologies, ANA, rheumatoid factor, double-stranded DNA. . .
    a. I think the differential diagnosis includes in descending order of probability immunization related autoimmune phenomenon which will probably be transient, possibility of long-lasting symptomatology is there and while it is not well reported in literature I have seen several cases of onset of lupus more often than onset of rheumatoid arthritis after immunization.

Exhibit 3 at 300026.

Dr. Gilhooly recommended "watchful waiting" and, among other things, a repeat of Ms. Campbell's "rheumatic serologies." Id. at 300026. Ms. Campbell was discharged from Munson Medical Center the same day, December 19, 2003. Exhibit 3 at 300017-19.

In conjunction with seeing Dr. Gilhooly, Ms. Campbell also saw Dr. Ball, whose speciality is not apparent. Dr. Ball determined that Ms. Campbell did not have a polyneuropathy of any type, ruling out such diseases as Guillain-Barré syndrome and chronic inflammatory demyelinating polyneuropathy. Dr. Ball agreed with Dr. Gilhooly that Ms. Campbell had a "rheumatological problem, probably precipitated / exacerbated by her recent Pneumovax/flu vaccines." Exhibit 3 at 300014.

The discharge report stated that two doctors had determined that "the primary component of [Ms. Campbell's] weakness was giveaway weakness due to lack of effort and some weakness due to pain rather than due to diminished strength or to diminished muscle coordination." Exhibit 3 at 300018.

On December 24, 2003, Ms. Campbell saw Dr. Jackson in his office for the third time in a month. His note about Ms. Campbell's extremities stated that there was "No active tenosynovitis. No edema." Dr. Jackson also reviewed some laboratory work from her December 19, 2003 hospitalization. Dr. Jackson had the impression that Ms. Campbell had "inflammatory arthritis, etiology indeterminate." Exhibit 1 at 100021.

Ms. Campbell returned to Dr. Gilhooly, her rheumatologist, on January 13, 2004. The reason for her follow-up appointment was "question post-vaccination immune phenomenon versus triggering of primary autoimmune phenomenon such as lupus, Sjogren's, or rheumatoid." Ms. Campbell reported that she had "No swelling, some warmth, stiffness in the morning [for] a half hour." The physical examination showed that Ms. Campbell had a "passive range of motion about the joints, slight tenderness at the extremes of right wrist extension, left elbow extension." Dr. Gilhooly did not note any swelling. Exhibit 3 at 300048.

Dr. Gilhooly's impressions included "Question autoimmune disease, undifferentiated. . . . Keep in mind Sjogren's [syndrome], lupus versus immune phenomenon simply triggered by the immunization that will gradually resolve." Dr. Gilhooly repeated certain tests. Id.

B. February 2004 and Later

In February 2004, Ms. Campbell saw Dr. Gilhooly again. Ms. Campbell reported that she "persists with bilateral MCP, MTP, and PIP pain and stiffness but no swelling. Variable morning stiffness but worsening as the day goes on. Worse with weight bearing and gripping activities." The physical examination seemed to confirm Ms. Campbell's report: "Tenderness to palpation of the MCPs, PIPs, and metatarsals as well as to squeeze but no active synovitis."[1]

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[1] These medical terms and abbreviations refer to hands, feet, fingers and toes. "MCP" is metacarpophalangeal (the hands). "MTP" is metatarsophalangeal (the feet). "PIP" is proximal interphalangeal joint (the fingers and toes). See Dorland's Illustrated Medical Dictionary (30th Ed. 2002) at 1135, 1138, 1413.

Dr. Gilhooly's impression included: "Question inflammatory arthritis; question forme fruste of lupus triggered by immunization." Dr. Gilhooly discussed starting Ms. Campbell on Plaquenil, but did not actually prescribe Plaquenil. Exhibit 3 at 300047. Plaquenil is a drug often given to treat inflammation. Tr. 73, tr. 305.

On March 11, 2004, Ms. Campbell returned to her primary care doctor, Dr. Jackson. Dr. Jackson's physical examination showed "No edema." His impressions included: "Generalized arthralgias and myalgias with working diagnosis of postinflammatory arthritis status post flu injection." Exhibit 1 at 100020.

On April 23, 2004, Ms. Campbell returned to Dr. Gilhooly. Dr. Gilhooly's typed office note from this visit states that Ms. Campbell was having a "follow up for undifferentiated connective tissue disease, ANA positive, rheumatoid factor negative, and hypergammaglobulinemia." Dr. Gilhooly observed that "There is tenosynovitis over extensor right wrist, MCPs, slight decreased fist formation . . . trace synovitis perhaps over the ankles." Exhibit 3 at 300046.

Dr. Gilhooly stated that Ms. Campbell could have "Sjogren's syndrome versus undifferentiated connective tissue disease." Dr. Gilhooly prescribed Plaquenil for Ms. Campbell at this time. Exhibit 3 at 300046.

Ms. Campbell's next follow-up visit with Dr. Gilhooly was on June 11, 2004. Dr. Gilhooly reported that Ms. Campbell was being seen for "inflammatory arthritis, positive ANA, status post pneumovax." Ms. Campbell reported that she had "scalp psoriasis." Ms. Campbell also reported that the Plaquenil was helping to some extent. Dr. Gilhooly's examination showed that Ms. Campbell had "PIPs and DIPs puffy and MCPs tender at the extremes as are wrists but no active synovitis. . . . Skin does demonstrate psoriasiform plaque in the scalp." Exhibit 3 at 300045.

Dr. Gilhooly diagnosed Ms. Campbell as having "probable psoriatic arthritis." This type of arthritis is also different from rheumatoid arthritis. Dorland's at 149, 156. Dr. Gilhooly continued the prescription for Plaquenil and wanted Ms. Campbell to return in approximately four months. Exhibit 3 at 300045.

On September 21, 2004, Ms. Campbell saw Dr. Gilhooly again. (The form for this visit differed from previous records from Dr. Gilhooly.) The reason for this visit was a "routine" follow up for "PA" and "FM." Exhibit 3 at 300041. Given Dr. Gilhooly's June 11, 2004 diagnosis, "PA" probably refers to "psoriatic arthritis." "FM" probably refers to fibromyalgia. Neil M. Davis, Medical Abbreviations (12th ed. 2005) at 148. At the conclusion of this report, Dr. Gilhooly indicated again that Ms. Campbell had psoriatic arthritis. Dr. Gilhooly wanted Ms. Campbell to return again in six weeks. Exhibit 3 at 300043.

Unfortunately, Dr. Gilhooly died sometime between September 21, 2004 and November 12, 2004. Exhibit 3 at 300041, id. at 300051. Ms. Campbell started to see a different rheumatologist.

Ms. Campbell was seen at the Harbor Arthritis Center on January 13, 2005 by Jane Denay.[2] Ms. Denay reported that there was no evidence of "an inflammatory arthropathy." Ms. Denay suggested that Ms. Campbell might have fibromylagia. Exhibit 3 at 300005.

Ms. Campbell has continued to see various doctors since January 2005. Details from these visits are less relevant to determining whether Ms. Campbell experienced an adverse reaction to the flu vaccine.

II. Procedural History

Ms. Campbell filed her petition on June 28, 2007, and filed an amended petition on August 31, 2007. With the amended petition, she submitted her first set of medical records and a report from Dr. Arthur Brawer, a rheumatologist. Dr. Brawer opined that Ms. Campbell's rheumatoid arthritis "was directly initiated by her influenza vaccination of December 4, 2003." Exhibit 10 at 10-5. Dr. Brawer attached one article to his report.

The parties attempted to resolve this case. However, they were not successful.

Respondent filed a report, pursuant to Vaccine Rule 4, and also a report by Dr. Robert Lightfoot, Jr. on March 20, 2008. With support from Dr. Lightfoot, respondent denied that Ms. Campbell was entitled to compensation. Respondent challenged the reliability of Dr. Brawer's opinion. Later, respondent filed literature cited by Dr. Lightfoot.

During a pre-trial conference, the parties agreed that the hearing would be limited to determining whether Ms. Campbell suffered an adverse reaction to the flu vaccine. The parties agreed that the hearing would not focus on a secondary question, namely, what sequella Ms. Campbell suffered as a result of an adverse reaction. The parties recognized that the question of sequella was complicated because Ms. Campbell's pre-existing conditions could have caused her to suffer some problems that she is currently experiencing even if she had not received the flu vaccine. Thus, the parties agreed to delay this analysis until after a finding that Ms. Campbell experienced an adverse reaction. Order, filed July 2, 2008.

On April 30, 2008, a hearing was scheduled to take place on July 10, 2008. This hearing was delayed to accommodate the schedule of Ms. Campbell's attorney.

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[2] Although Ms. Campbell's amended petition refers to Ms. Denay as "Dr. Denay," the letter indicates that Ms. Denay is a Certified Family Nurse Practitioner. Ms. Denay worked in an office with at least one doctor certified in rheumatology. Exhibit 3 at 300005. Whether a doctor also saw Ms. Campbell is not clear.

The delay in the hearing allowed both parties to file additional material. Ms. Campbell submitted a supplemental report from Dr. Brawer and some additional medical articles. Exhibits 16-22. Respondent filed one additional article, exhibit E. Respondent also explained that he did not contend that the pneumococcal vaccine caused Ms. Campbell's rheumatoid arthritis. Resp't Status Rep't, filed Sept. 26, 2008. Finally, two business days before the hearing, Ms. Campbell filed five additional articles. Exhibits 23-27.

A hearing was held on October 21, 2008, in New York, New York. As discussed above, the hearing was limited to whether Ms. Campbell suffered an adverse reaction. The two witnesses were Dr. Brawer and Dr. Lightfoot. Due to the length of the testimony, a second day of hearing was required. It was held on January 15, 2009, in Washington, D.C.

At the end of the hearing, the parties were offered an opportunity to file a brief after the hearing. The respondent deferred to Ms. Campbell's attorney. Neither party opted to file a brief after the hearing. Thus, the case is ready for adjudication.

III. Analysis

A. Introduction

1. Standards for Adjudication

To receive compensation under the Program, Ms. Campbell must prove either: (1) that she suffered a "Table Injury"--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of her vaccinations, or (2) that she suffered an injury that was actually caused by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, Ms. Campbell does not claim that she suffered a table injury. Thus, she must prove causation in fact.

To prove causation in fact, a petitioner must establish at least three elements. The petitioner's

> burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (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). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

A petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material contained in the record. 42 U.S.C. § 300aa-13(b)(1). This universe necessarily includes "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation . . . of the petitioner's illness." 42 U.S.C. § 300aa-13(b)(1)(A). Here, Ms. Campbell has submitted her medical records as well as the opinion of Dr. Brawer.

In this case, the evidence includes conflicting opinions from each side's experts. The persuasiveness of the experts must be evaluated and the testimony of one side's expert may be rejected when a reasonable basis supports such a rejection. Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993). A decision about the persuasiveness of a witness is virtually not reviewable on appeal. Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993); see also Energy Capital Corp. v. United States, 302 F.3d 1314, 1329 (Fed. Cir. 2002) ("As for the relative weight given to the testimony of both sides' expert witnesses, we accord the trial court broad discretion in determining credibility because the court saw the witnesses and heard their testimony.").

2. Summary of Expert Opinions

Here, Dr. Brawer and Dr. Lightfoot agree about one fundamental point – Ms. Campbell currently suffers from rheumatoid arthritis. However, Dr. Brawer and Dr. Lightfoot disagree about the cause of the rheumatoid arthritis. Dr. Brawer believes that the flu vaccine cross-reacted with antigens in Ms. Campbell's body (a process known as molecular mimicry) to cause rheumatoid arthritis. Exhibit 10 at 6; exhibit 16 at 1; tr. 20.

In contrast, Dr. Lightfoot believes that the flu vaccine does not cause rheumatoid arthritis. Dr. Lightfoot states that no study has linked rheumatoid arthritis and the flu vaccine. Exhibit A at 6-8.

In addition, Dr. Lightfoot believes that pre-existing conditions may have contributed to Ms. Campbell's health problems after the vaccination. Dr. Lightfoot points to her rotator cuff disease in her shoulders and her degenerative joint disease in her cervical and lumbar spines. Exhibit A at 1-3.

3. General Evaluation of the Experts

Dr. Lightfoot was more persuasive than Dr. Brawer. Several factors contribute to this conclusion.

Dr. Lightfoot has more experience in rheumatology and has a "sterling" reputation among rheumatologists. Tr. 176. The distinction between the two can be seen in different ways. For

example, Dr. Brawer led a professional organization of rheumatologists for the state of New Jersey. Tr. 171. Dr. Lightfoot led a professional organization of rheumatologists for roughly one quarter of the United States. Tr. 222-23. Dr. Brawer is a fellow in the American College of Rheumatology (as is Dr. Lightfoot), Tr. 11, tr. 222. Dr. Lightfoot is a master in that organization, a distinction conferred on only a limited number of doctors each year. Tr. 222.

Within the field of rheumatology, Dr. Lightfoot has specialized in treating people with rheumatoid arthritis. Tr. 226. He has published extensively in this field.

In addition, the demeanor of the experts favored Dr. Lightfoot. Dr. Lightfoot appeared receptive to the undersigned's inquiries and displayed an attitude of wanting to impart knowledge. Dr. Brawer seemed more concerned with expressing his own point of view, almost like an advocate. See tr. 142 (Dr. Brawer discussing Daubert).

A final factor, although this factor is relatively less important than the other factors, is their histories as expert witnesses. Dr. Lightfoot has participated in litigation, relatively rarely. Tr. 227. This infrequency suggests that Dr. Lightfoot is relatively selective about participating in cases and that he does not derive a significant portion of his income from working as an expert witness.

In contrast, Dr. Brawer participates in litigation more commonly. He estimated that eight percent of his income came from activities related to litigation. Tr. 15. In two cases, judges rejected Dr. Brawer's opinions because they did not meet the requirements established in Daubert. Polston v. McGhan Medical Corp., No. 05-98-00510-CV, 2000 WL 688216, at *6 (Tex. App. - Dallas May 22, 2000) (not designated for publication); Bailey v. Dow Corning Corp., No. 94-1199-A, 1996 WL 937659 (Tex. Dist. Sept. 6, 1996); see also tr. 456-57 (Dr. Brawer discussing these cases). These cases do not strengthen Dr. Brawer's overall impression.

All these factors contribute to the finding that Dr. Lightfoot was more persuasive than Dr. Brawer. They also underlie the analysis of the three factors from Althen, which is set forth in the following section. However, this general assessment is not repeated within the following three sections.

B. A Medical Theory Causally Connecting the Vaccination and the Injury

The first prong from Althen is "a medical theory causally connecting the vaccination and the injury." Ms. Campbell has failed to meet her burden of proof on this element.

In the Vaccine Program, an expert's opinion may be evaluated according to the factors identified by the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Terran v. Sec'y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999). As recognized in Terran, the Daubert factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and, (4) whether the theory or technique enjoys general acceptance within a relevant scientific community

Terran, 195 F.3d at 1316 n.2, citing Daubert, 509 U.S. at 592-95.

As part of his opinion, Dr. Brawer offered various theories for how the influenza vaccine can cause rheumatoid arthritis.[3] Dr. Brawer began by offering the general point that live viruses can cause autoimmune diseases and that vaccines are "pretty much" the same thing as a natural infection. Tr. 21-23. Dr. Brawer also posited some specific theories. His primary theory was molecular mimicry. Tr. 26-27, tr. 30. He also offered some other theories, including (1) the theory that the vaccine leads to the production of immune complexes, (2) the theory that the vaccine prompts an aberrant amount of cytokines, and (3) the theory that the vaccine leads to a proliferation of B-cells. Tr. 30, tr. 38-40.[4]

A general problem with Dr. Brawer's theories is that Dr. Brawer did not explain them very well. For example, even if the influenza vaccine can cause a person, such as Ms. Campbell, to produce immune complexes, how does the production of immune complexes cause rheumatoid arthritis?[5] Dr. Brawer appears not to have developed his thoughts about the different theories completely. Dr. Brawer's list of theories appears to be just that – a list, which Dr. Brawer has proposed without placing them into the context of Ms. Campbell's case.

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[3] Dr. Brawer testified that he believed that the pneumococcal vaccine did not cause Ms. Campbell's rheumatoid arthritis because he was not aware of any case reports associating the two. Tr. 129, tr. 214. As mention earlier, respondent did not contend that the pneumococcal vaccine caused Ms. Campbell's rheumatoid arthritis. Resp't Status Rep't, filed Sept. 26, 2008.

[4] In the context of discussing different theories, Dr. Brawer also mentioned that the vaccine contains a preservative. Tr. 44. This statement is not a theory. It is a fact.

[5] By way of contrast, a petitioner was entitled to compensation based upon a theory involving "immune complexes." In that case, petitioner's expert theorized that the immune complexes deposited into the petitioner's kidneys, the deposit caused inflammation, the body responded to the inflammation by attacking itself, and this attack on self caused the petitioner to suffer Wegener's granulomatosis. Fields v. Sec'y of Health & Human Servs., No. 02-311V, 2008 WL 2222141, at *6-10 (Fed. Cl. Spec. Mstr. May 14, 2008).

As explained in the text, Dr. Brawer's proposed theories are so superficial that Ms. Campbell has not demonstrated their reliability or their persuasiveness.

Respondent's cross-examination of Dr. Brawer gave Dr. Brawer an opportunity to develop his ideas about molecular mimicry. Tr. 133-46. He also discussed this theory when he testified in rebuttal. Tr. 441-43.

Molecular mimicry is a fairly well known theory. Petitioners in the Vaccine Program often contend that a particular vaccine caused an adverse reaction because of molecular mimicry. Advocates of this theory hypothesize that the molecular structure of the vaccine resembles (or mimics) the structure of part of the body. Thus, when the body responds to the vaccine, a portion of the body's immunologic response is confused and attacks the body's own tissues. Tr. 194. This theory has existed for more than 30 years. According to Dr. Brawer, molecular mimicry has never been proven or disproved. Tr. 26-27.

Ms. Campbell has not established, by a preponderance of the evidence, that molecular mimicry is a reliable theory to explain how the flu vaccine can cause rheumatoid arthritis. As defined by the Federal Circuit, Ms. Campbell must demonstrate "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278 (emphasis added). The emphasized portion indicates that the medical theory must focus on the specific vaccine and the specific injury at issue. Thus, even if molecular mimicry were established as reliable in one context, that finding would not necessarily mean that molecular mimicry is valid for all vaccines and all injuries.

Pursuant to Daubert and pursuant to Terran, which approved the special master's use of Daubert factors in evaluating the reliability of an expert's theory, one factor to consider is whether the expert's theory can be tested. Here, Dr. Brawer suggested that molecular mimicry could not be tested. In particular, Dr. Brawer stated that amino acid sequences that comprise the influenza vaccine could not be analyzed to see if they matched the amino acid sequences that comprise the synovial fluid. Tr. 193-95.

Dr. Brawer's response shows a weakness and lack of reliability of his theory. If his theory is not testable, then Daubert seems to indicate that this lack of testability suggests unreliability. See Gilson v. Sirmons, 520 F.3d 1196, 1242 (10th Cir. 2008) (affirming district court's exclusion of an expert's testimony when there was no showing that the theory was generally accepted or could be tested).

On the other hand, Dr. Brawer's assertion that it is not possible to test the molecular structure of the influenza vaccine and the molecular structure of the synovial fluid is doubtful. Although Dr. Lightfoot did not address Dr. Brawer's assertion, a finder of fact is not required to accept unrebutted testimony of an expert. Applied Medical Resources Corp. v. United States Surgical Corp., 147 F.3d 1374, 1379 (Fed. Cir. 1998). Special masters may use accumulative expertise to evaluate evidence. Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1362 (Fed. Cir. 2000), quoting Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993); see also Sword v. Sec'y of Health & Human Servs., 44 Fed. Cl. 183 (1999).

In many other cases, petitioners' experts have asserted molecular mimicry between a vaccine and a condition suffered by petitioners. When these experts have been persuasive, they have usually shown some similarity in molecular structure between a portion of the vaccine and a portion of a relevant body part. Dr. Brawer's failure to do the same lessens the reliability of his opinion that molecular mimicry explains the connection between the influenza vaccine and rheumatoid arthritis.

Ms. Campbell has also not established the reliability of the other theories mentioned by Dr. Brawer. These other theories include immune complexes, cytokines, and B-cells. Ms. Campbell is not required to establish these theories to a level of medical certainty. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543 (Fed. Cir. 1994). However, the theory "must be supported by a sound and reliable medical or scientific explanation." Id. at 548. Ms. Campbell failed to introduce any persuasive evidence to support Dr. Brawer's assertion that these theories are a "sound and reliable" means to explain how the flu vaccine can cause rheumatoid arthritis.

Ms. Campbell may have intended to use the various medical articles she filed to support one or more of Dr. Brawer's theories. Ms. Campbell was not required to submit peer-reviewed articles. Althen, 418 F.3d at 1281. But, Ms. Campbell did submit these articles. Because special masters are required to evaluate the record "as a whole;" 42 U.S.C. § 300aa–13; these articles have been considered. The medical articles that were presented are not persuasive in establishing a "sound and reliable" medical theory as required by Knudsen, 35 F.3d at 548.

The overarching problem with the medical articles presented by Ms. Campbell is that they are generally case reports. See exhibits 23, 24, 25, 27, 32, 33. The articles primarily assert that a patient developed rheumatoid arthritis after receiving a vaccination. On their face, the articles do not assert a causal connection between the vaccine and the rheumatoid arthritis. Id. Case reports have relatively little persuasive value in establishing causation. Tr. 161-63 (Dr. Brawer), tr. 310 (Dr. Lightfoot). Legal precedents also recognize that case reports have little reliability in establishing causation. See, e.g., McClain v. Metabolife Intern., Inc., 401 F.3d 1233, 1253 (11th Cir. 2005); Meister v. Medical Engineering Corp., 267 F.3d 1123, 1129 (D.C. Cir. 2001); Glastetter v. Novartis Pharmaceuticals Corp., 252 F.3d 986, 989-90 (8th Cir. 2001).

A weakness in case reports is that they present a chronological picture only. For example, in the case reports submitted as exhibits in Ms. Campbell's case, a person received a vaccine and then developed a disease. Generally, case reports cannot exclude the possibility that the disease developed coincidentally after the vaccination.

Dr. Lightfoot explained how the general point that some diseases might appear after a particular event applied to rheumatoid arthritis after flu vaccine. Dr. Lightfoot started with the estimated number of new cases of rheumatoid arthritis each year in the United States, then divided this figure by 365 to determine how many new cases of rheumatoid arthritis develop in the United States each day. The result is 332 new cases per day. Tr. 424.

New cases of rheumatoid arthritis are relatively common. Tr. 265. Administrations of the flu vaccine are also relatively common. Purely by chance, some people who develop rheumatoid arthritis will have received a flu vaccination within the previous 30 days. Tr. 422-27. Thus, the temporal association between the receipt of a flu vaccine and the development of rheumatoid arthritis in some people does not demonstrate that the flu vaccine caused the rheumatoid arthritis. Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992).

For these reasons, Ms. Campbell has failed to show that Dr. Brawer's theory is "supported by a sound and reliable medical or scientific explanation." Knudsen, 35 F.3d at 548. Thus, she is not entitled to compensation.[6]

C. Temporal Association

The third prong from Althen is "a showing of a proximate temporal relationship between vaccination and injury." Although this is the third prong listed, analyzing this factor as the second factor simplifies the analysis of this case.

Dr. Brawer stated that Ms. Campbell's case demonstrates an appropriate temporal relationship. Tr. 57-59; exhibit 16 at 2. Dr. Brawer stated that the reports about a vaccine against a virus (as opposed to a bacterium) show that the expected lapse of time before the person will display symptoms of the disease is 2-14 days. Tr. 52.

Dr. Brawer opined that Ms. Campbell showed signs and symptoms of rheumatoid arthritis within 48 hours after receiving the flu vaccine. Tr. 58-59. To Dr. Brawer, Ms. Campbell's rheumatoid arthritis began on December 6, 2003. Tr. 117-18.

Even if Dr. Brawer's opinion that the appropriate time frame expected by medical science is 2-14 days were assumed to be accurate, Ms. Campbell has not demonstrated that her rheumatoid arthritis began in this window. Dr. Brawer's opinion that her rheumatoid arthritis began during this time is not persuasive for several reasons.[7]

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[6] The Federal Circuit affirmed a special master's factual determination that the hepatitis B vaccine can cause rheumatoid arthritis. Capizzano, 440 F.3d at 1322, 1325. This decision does not control the outcome in this case because the evidence – including the vaccine at issue – differed.

[7] Whether a person is displaying signs or symptoms of a disease is different from whether a person is properly diagnosed with that disease. Ms. Campbell could not be diagnosed as suffering from rheumatoid arthritis on December 8, 2003, because she did not fulfill the criteria as established by the American Rheumatological Association. Tr. 115-16. One of the criteria is that symmetrical pain and swelling in the joints lasts longer than six weeks. Tr. 62.

If Ms. Campbell had begun to experience swelling in her joints in early December 2003, a

One simple reason is that Dr. Lightfoot did not agree with Dr. Brawer. Dr. Lightfoot opined that he could not determine when Ms. Campbell's rheumatoid arthritis began. Tr. 242. Given the general differences between Dr. Lightfoot and Dr. Brawer as described in section III.A.3 above, Dr. Lightfoot's opinion is more persuasive.

However, the finding that Ms. Campbell has not established that her rheumatoid arthritis began within 2-14 days after she received the flu vaccination does not rest simply on the qualifications of the experts. This finding also flows from the reasoning employed by Dr. Lightfoot. Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375 (Fed. Cir. 1994).

People suffering from rheumatoid arthritis have a constellation of signs and symptoms. A simple definition is chronic inflammation in the peripheral joints. Tr. 234. People with rheumatoid arthritis have swelling in their hands and swelling in other joints as well. The swelling should also appear symmetrically, such as right knee and left knee. Various tests will also show that a person with rheumatoid arthritis has a positive rheumatoid factor, rheumatoid nodules, and erosions of their joints when viewed by X-ray. Tr. 62, tr. 270-72.

Ms. Campbell presented little persuasive evidence that she was suffering from inflammation in her joints within two weeks (14 days) after vaccination. One piece of evidence in Ms. Campbell's favor is Dr. Jackson's discharge summary from December 10, 2003. Dr. Jackson's final diagnosis was "Acute bilateral upper extremity inflammatory arthritis." Exhibit 2 at 200092. However, Dr. Jackson did not prescribe any medications usually given to treat inflammatory arthritis. Tr. 422.

Dr. Jackson's diagnosis is worthy of some consideration because it is a statement of a treating physician. See Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280).[8]

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doctor would have been unlikely to diagnose Ms. Campbell as suffering from rheumatoid arthritis because the swelling in her joints had not lasted long enough. However, the doctor would probably have noted the swelling in her joints.

If Ms. Campbell had begun to experience swelling in her joints in December 2003, and if this swelling continued for more than six weeks, then a doctor, in February 2004, could diagnose Ms. Campbell as having rheumatoid arthritis beginning in December 2003, approximately six weeks earlier. When Ms. Campbell's symptoms began is more important than when she is diagnosed. As explained in the text, a deficiency with Ms. Campbell's case is that there is an insufficient amount of evidence to establish that she suffered inflammation in her joints in the time expected by Dr. Brawer.

[8] Citing Althen, Capizzano attaches greater weight to the opinions of treating doctors than Althen actually provides. Althen states that 42 U.S.C. § 300aa–13(a)(1) allows "medical opinion as proof" of causation. Althen, 418 F.3d at 1280.

Althen does not state that "medical records and medical opinion testimony are favored in vaccine cases." Nor does Althen state that "treating physicians are likely to be in the best

However, his statement is not dispositive. "Any such diagnosis [contained in the record] . . . shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, . . . the special master shall consider the entire record and the course of the injury." 42 U.S.C. § 300aa–13(b).

Materials within the "entire record" raise questions about the accuracy of Dr. Jackson's December 10, 2003 diagnosis. Dr. Jackson anticipated that a consultation with a rheumatologist might be necessary to provide a more complete diagnosis. Exhibit 2 at 200094.

Dr. Jackson did not provide a basis for his conclusion that Ms. Campbell suffered from inflammatory arthritis. He may have considered that her upper extremities were swollen and filled with fluid. Exhibit 2 at 200100; tr. 241. This type of swelling is not consistent with the usual presentation of rheumatoid arthritis because the report suggests that Ms. Campbell had swelling throughout her upper arms, not just in the joints. Tr. 241. Dr. Jackson may have also considered that Ms. Campbell's test for ANA was positive. However, a positive ANA is not diagnostic for rheumatoid arthritis. Tr. 106-07, tr. 243-44.

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position" to determine causation in vaccine cases. Giving a statement from a treating doctor more weight merely because the doctor is a treating doctor appears problematic.

First, establishing a presumption that statements from treating doctors are entitled to more weight may create an inconsistency with the statute. Section 13(b)(1) requires the special master to consider "any . . . medical judgment . . . which is contained in the record regarding the . . . causation . . . of the petitioner's illness." This direction is qualified, however, by another portion of the same section. "Any such . . . judgment . . . shall not be binding on the special master or court. In evaluating the weight to be afforded to any such . . . judgment, . . . the special master or court shall consider the entire record." The distinction between "binding" and "favored" may be elusive.

Second, Capizzano did not explain why treating doctors should be favored in all cases. The Federal Circuit has acknowledged that the Office of Personnel Management and the Merit Systems Protection Board may evaluate opinions of treating doctors by considering "doubts about professional competence, contrary medical evidence, failure of the professional to consider relevant factors, lack of particularity in relating diagnosis to nature and extent of disability." Vanieken-Ryals v. Office of Personnel Management, 508 F.3d 1034, 1042 (Fed. Cir. 2007). These concerns about how doctors evaluate claims for disability retirement are valid concerns about how doctors determine causation in the Vaccine Program.

Third, as a practical matter, favoring the reports of all treating physicians may be impossible. Here, one treating doctor, Dr. Jackson, diagnosed Ms. Campbell as having "inflammatory arthritis." Exhibit 2 at 200092. Yet, another treating doctor, Dr. Gilhooly, diagnosed Ms. Campbell as having "reactive arthritis." Exhibit 3 at 300026. When two treating doctors come to different conclusions, the persuasiveness of each report must be evaluated.

As anticipated by Dr. Jackson when he discharged Ms. Campbell on December 10, 2003, Ms. Campbell was examined several times by different doctors. One of the doctors who saw Ms. Campbell was Dr. Gilhooly, a rheumatologist.

Because Dr. Gilhooly trained specifically in rheumatology, her expertise and views as to whether Ms. Campbell suffered from rheumatoid arthritis are especially persuasive. See tr. 334 (Dr. Lightfoot stating that he defers to the observation of a rheumatologist as to whether Ms. Campbell developed synovitis.). Dr. Gilhooly, the rheumatologist, reported "No synovitis was appreciated on examination." Exhibit 3 at 300026 (Dec. 19, 2003). Synovitis essentially is the inflamation of the inner layers of the membranes surrounding a joint. Dorland's at 1119, 1839; see also tr. 82. A reasonable inference is that because there was no synovitis at the time of Dr. Gilhooly's examination of Ms. Campbell, Dr. Gilhooly did not diagnose rheumatoid arthritis. Dr. Gilhooly suspected that Ms. Campbell may have had "reactive arthritis." Id. Reactive arthritis differs from rheumatoid arthritis. Tr. 67, tr. 318. Reactive arthritis does not develop into rheumatoid arthritis. Tr. 319.

Dr. Gilhooly's observation that Ms. Campbell did not suffer from inflammation in her joints was essentially confirmed by Dr. Jackson five days later. Dr. Jackson stated "No active tenosynovitis. No edema." Exhibit 1 at 100021 (Dec. 24, 2003).

Ms. Campbell received the flu vaccine on December 4, 2003. Exhibit 6; exhibit 1 at 100024-25. According to Dr. Brawer, Ms. Campbell should have begun to experience the signs and symptoms of rheumatoid arthritis by December 18, 2003. See tr. 52, tr. 58-59. However, a preponderance of the evidence establishes that Ms. Campbell was not experiencing swelling in her joints – the hallmark of rheumatoid arthritis – within the time expected by Dr. Brawer. Therefore, Ms. Campbell has failed to meet her burden of proof on this issue.

Once it is found that the Ms. Campbell did not develop rheumatoid arthritis within the time predicted by her expert's theory, Ms. Campbell's subsequent medical history diminishes in relevance. Although Dr. Lightfoot recognized that Ms. Campbell has rheumatoid arthritis in 2008, he did not know when she first began to suffer from rheumatoid arthritis. Tr. 305; see also tr. 230, tr. 242.[9]

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[9] Dr. Lightfoot suggested that Ms. Campbell displayed some signs of rheumatoid arthritis before the vaccination. Specifically, Ms. Campbell reported having problems with some joints, such as her ankle, and reported swelling in her joints. Tr. 242, discussing exhibit 1 at 100027 (August 1, 2003). This suggestion does not affect the outcome of this case. If it were true that Ms. Campbell displayed some signs of rheumatoid arthritis before being vaccinated, Ms. Campbell could have alleged that the flu vaccine significantly aggravated her underlying rheumatoid arthritis.

However, Ms. Campbell did not allege this theory and did not present any evidence to support it. Dr. Brawer stated that Ms. Campbell did not suffer from rheumatoid arthritis before she received the flu vaccine. Tr. 107.

Dr. Gilhooly's notations about "inflammatory arthritis" do not assist Ms. Campbell for several reasons. First, in February 2004, Dr. Gilhooly's diagnosis included: "Question inflammatory arthritis." Exhibit 3 at 300047. The word "Question" obviously indicates that the diagnosis is not clear to Dr. Gilhooly. Inflammatory arthritis may not have been an appropriate diagnosis in February 2004, because Ms. Campbell had "no active synovitis," according to Dr. Gilhooly's examination. Id.

Second, on April 23, 2004, Dr. Gilhooly noted during the physical examination that Ms. Campbell had "tenosynovitis over extensor right wrist, MCP, [and] . . . trace synovitis perhaps over the ankles." Dr. Gilhooly's impression did not include a diagnosis of rheumatoid arthritis. Rather, Dr. Gilhooly believed that Ms. Campbell suffered from "Sjogren's syndrome versus undifferentiated connective tissue disease." Exhibit 3 at 300046.

Even if the February 25, 2004 examination was assumed to constitute an onset of rheumatoid arthritis, this onset would have occurred outside the temporal window predicted by Dr. Brawer. The April 23, 2004 report is even farther removed.

For these reasons, a preponderance of the evidence supports a finding that Ms. Campbell was not experiencing swelling in her joints for two weeks after she received the flu vaccination. This finding means that Ms. Campbell was not experiencing rheumatoid arthritis within the time predicted by Dr. Brawer. Therefore, Ms. Campbell is not entitled to compensation. See Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1358 (Fed. Cir. 2006) ("If, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame.").

D. Logical Sequence of Cause and Effect

The remaining prong from Althen is "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Given that Ms. Campbell has failed to establish her burden with regard to the first element from Althen (medical theory) and with regard to the third element from Althen (timing), discussing this element is not necessary. However, some discussion remains appropriate.

As previously mentioned, the Federal Circuit has instructed special masters to consider the opinions expressed by treating doctors as to whether a vaccine has caused an injury. Capizzano, 440 F.3d at 1326. For Ms. Campbell, the statements by treating doctors do not satisfy Ms. Campbell's burden of establishing this element.

Generally, the statements of Ms. Campbell's treating physicians are not clear statements that the flu vaccine caused Ms. Campbell to develop rheumatoid arthritis. In general, there are two problems. First, Ms. Campbell received two vaccines on December 4, 2003. Although some records, particularly Dr. Gilhooly's records, suggest that a vaccination caused an adverse reaction, the records are ambiguous in that they mention the flu vaccine and the pneumococcal

(PPV) vaccine.[10] Examples include Dr. Gilhooly's December 19, 2003 report. Exhibit 3 at 300024-27; see also tr. 128 (discussing this entry), tr. 429 (same). In another report, Dr. Gilhooly describes Ms. Campbell as seeking follow up treatment for "inflammatory arthritis, positive ANA status post pneumovax." Exhibit 3 at 300045 (report dated June 11, 2004).

The second general limitation on the statements of Ms. Campbell's treating doctors is that they sometimes did not say that the vaccination "caused" a problem. Instead, the doctors presented a chronology. The treating doctors reported that Ms. Campbell experienced a problem after receiving the flu vaccine. See exhibit 1 at 100020 (Dr. Jackson's report dated March 11, 2004). There is a difference between saying the illness occurred "after" the vaccination and the illness "was caused by" the vaccination. Moberly v. Sec'y of Health & Human Servs., 85 Fed. Cl. 571, 604-5 (2009); Caves v. Sec'y of Health & Human Servs., No. 07-443V, 2008 WL 5970976, at *7-8 (Fed. Cl. Spec. Mstr. Nov. 25, 2008).

Similarly, some doctor's reports state that a reaction to a vaccine was "possible." Exhibit 1 at 100021-22 (Dr. Thad Jackson's report, dated Dec. 19, 2003); see also tr. 428 (discussing this report).

Dr. Gilhooly's December 20, 2003 note warrants particular attention. Her report literally states:

> IMPRESSION:
> 1. Post vaccination reactive arthritis. question myalgiae. weakness in a woman with positive serologies, ANA, rheumatoid factor, double-stranded DNA and a possible antecedent history of some ear symptomatology that may or may not be relevant with chronic steatohepatitis.

Exhibit 3 at 300026; see also tr. 347 (discussing this report).

This report does not assist Ms. Campbell. Dr. Gilhooly has suggested that Ms. Campbell has reactive arthritis. As explained above, reactive arthritis is not the same as rheumatoid arthritis. Tr. 318-19.[11]

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[10] Ms. Campbell may not seek compensation for the pneumococcal vaccine because it is not listed on the Vaccine Injury Compensation Table. 42 C.F.R. § 100.3; 66 Fed. Reg. 28166, 28166.

[11] Although medical records are usually accepted at face value, Dr. Lightfoot presented a fair explanation for why Dr. Gilhooly's written report may contain an error. Dr. Lightfoot stated that "myalgia" either is present or it is not present. "Myalgia" is not usually "questionable." Dr. Lightfoot suggested that Dr. Gilhooly probably intended to communicate that there should be a question mark after the phrase "post vaccination reactive arthritis". Tr. 416.

However, resolving whether Dr. Gilhooly's report was accurately transcribed is not necessary. (Dr. Gilhooly's death prevents any clarification on this point.) Even if the report

Although these problems explain why many statements of Ms. Campbell's doctors are not persuasive, some doctors' reports more clearly support a finding of entitlement. For example, Dr. Jackson stated that Ms. Campbell was "positive for severe adverse reaction to influenza vaccine last year requiring hospitalization." Dr. Jackson made this statement on November 12, 2004, approximately one year after Ms. Campbell received the flu vaccine. Exhibit 1 at 100013;[12] see also tr. 212 (discussing this entry), tr. 344-46 (same), tr. 429 (same).

Although supportive of Ms. Campbell's position, Dr. Jackson's November 12, 2004 report does not satisfy Ms. Campbell's burden of proof. His November 12, 2004 report is a stronger statement of causality than his December 19, 2003 report, which stated that a vaccine reaction was "possible." Exhibit 1 at 100021-22. But, Dr. Jackson did not explain why his opinion evolved. In addition, Dr. Campbell's November 12, 2004 report must be considered in the context of all the records, including Dr. Gilhooly, whose records are discussed above.

As a matter of logic, after Ms. Campbell failed to establish a reliable medical theory and failed to establish an appropriate temporal relationship, she cannot establish a logical sequence of cause and effect showing that the flu vaccine was the cause of her rheumatoid arthritis. The statements of the treating doctors, taken collectively, do not assist Ms. Campbell in meeting her burden of proof on this element.

IV. Conclusion

Ms. Campbell has failed to establish any of the elements required by Althen. Thus, she is not entitled to compensation. The Clerk's Office is ordered to enter judgment in accord with this opinion unless a motion for review is filed.

IT IS SO ORDERED.

S/ Christian J. Moran

Christian J. Moran
Special Master

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were accurate as transcribed, Dr. Gilhooly's report is not persuasive evidence that the flu vaccine caused Ms. Campbell's rheumatoid arthritis for reasons explained in the text.

[12] A duplicate of this record appears as exhibit 3 at 300050.