# In the United States Court of Federal Claims

No. 07-465V

(Filed: October 26, 2009)

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| FRANCES CAMPBELL,<br><br>Petitioner,<br><br>v.<br><br>SECRETARY OF HEALTH AND HUMAN SERVICES,<br><br>Respondent. | ) | Vaccine case; off-Table claim stemming from rheumatoid arthritis allegedly caused by trivalent influenza vaccine; required elements of proof; causation |

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## OPINION AND ORDER[1]

LETTOW, Judge.

Petitioner, Frances Campbell, seeks review of a decision by a special master dated July 7, 2009, denying her compensation under the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 311, 100 Stat. 3743, 3755 (1986) (codified, as amended, at 42 U.S.C. §§ 300aa-

[1]In accord with the Rules of the Court of Federal Claims ("RCFC"), App. B, Rule 18(b), this opinion and order is initially being filed under seal. By rule, the parties are afforded fourteen days in which to propose redactions.

1 to -34) ("Vaccine Act"). Ms. Campbell alleges that her injection with a trivalent influenza vaccine in 2003 caused the onset of her rheumatoid arthritis. *See Campbell v. Secretary of Health & Human Servs.*, No. 07-465, 2009 WL 2252550, at *1 (Fed. Cl. Spec. Mstr. July 7, 2009) ("Entitlement Decision").

This is a so-called off-Table vaccine injury case in which the claimant must establish causation in fact.[2] The parties do not dispute that Ms. Campbell suffers from rheumatoid arthritis, an autoimmune disease. However, causation is at issue. The special master denied relief to Ms. Campbell on the grounds that she "has not established that the theories offered by her expert [to explain how the influenza vaccine could cause the onset of rheumatoid arthritis] are reliable," and "even if her expert's theories were reliable, [that] she experienced signs and symptoms of rheumatoid arthritis within the time predicted by her expert." Entitlement Decision at *1. The decision of the special master to deny Ms. Campbell compensation was based primarily on two findings: (1) that respondent's expert, Dr. Lightfoot, was more credible than petitioner's expert, Dr. Brawer, *see id*. at *7; and (2) that the contemporaneous notes of

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[2]Trivalent influenza vaccine appears on the Vaccine Injury Table maintained by the Secretary of Health and Human Services pursuant to statute, *see* 42 C.F.R. § 100.3 (2008), as adopted and revised pursuant to the authority of 42 U.S.C. § 300aa-14(c). Provision XIII of the Table lists "[a]ny new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage." 42 C.F. R. § 100.3(a) Table, Provision XIII. By a notice published on April 12, 2005, "the Secretary announce[d] that trivalent influenza vaccines are covered vaccines under the National Vaccine Injury Compensation Program." *National Vaccine Injury Compensation Program: Application of Trivalent Influenza Vaccines to the Vaccine Injury Table*, 70 Fed. Reg. 19092 (Apr. 12, 2005). As the Secretary explained:

> [T]wo types of influenza vaccines are routinely given to millions of individuals in the United States each year. One is an activated (killed) virus vaccine administered using a syringe, while the other is a live, attenuated product administered in a nasal spray. Both vaccine types are trivalent, meaning that they contain three vaccine virus strains which are thought most likely to cause disease outbreaks during the influenza season.

*Id*.

However, no Table injuries are specified for this vaccine. *See* 42 C.F.R. § 100.3(a) Table, Provision XIII. For most listed vaccines, "[t]he Table lists symptoms and injuries associated with each listed vaccine and a timeframe for each symptom or injury." *de Bazan v. Secretary of Health & Human Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008). If a listed symptom occurs after vaccination within the specified timeframe, causation is presumed. *Id*. Injuries not listed in the Table or injuries that occur outside the specified timeframe following vaccination are deemed "off-Table" injuries, and causation is not presumed in such cases. *Id*. In this instance, however, because no injuries are specified for trivalent influenza vaccine, all claims related to that vaccine are off-Table injuries.

Ms. Campbell's treating physicians failed to establish that her influenza vaccination caused the onset of her rheumatoid arthritis. *See id.* at *14-15. Both findings are challenged by petitioner.

## FACTS[3]

Frances Campbell was born in August of 1957. Entitlement Decision at *1. At the time she received the influenza vaccine on December 4, 2003, Ms. Campbell had several pre-existing medical conditions. Orthopedically, Ms. Campbell had (i) clinical and radiographic osteoarthritis in her cervical and lumbar spine,[4] (ii) radiographic osteoarthritis at the first metacarpophalangeal joint in her right hand, (iii) osteoarthritis in her left knee resulting from a torn meniscus, (iv) osteoarthritis in her right shoulder resulting from its overuse, and (v) "[p]ersistent pain and progressive limitation of motion" in her left shoulder, for which she underwent three arthroscopies, resulting from a work-related injury. R. Ex. 10 at 10-2. In addition to these orthopedic conditions, Ms. Campbell had non-alcoholic steatohepatitis[5] and mild fibrosis (formation of fibrous tissue) in her liver, revealed by a biopsy in 2001 and elevated liver function tests in 2000 or 2001. R. Ex. 10 at 10-1 to 10-2; *Dorland's* at 712. Ms. Campbell also tested positive for antinuclear antibodies ("ANA")[6] in 2001 and continued to have positive ANA tests through December of 2003. R. Ex. 10 at 10-2.

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[3]In this recitation of the facts, the transcript of the entitlement hearing before the special master will be cited as "Tr. __" and references to documentary materials made part of the record will be to "R. Ex. __ at __."

[4]Osteoarthritis is "a noninflammatory degenerative joint disease seen mainly in older persons . . . [that is] accompanied by pain, usually after prolonged activity, and stiffness, particularly in the morning or with inactivity." *Dorland's Illustrated Medical Dictionary*, 1365 (31st ed. 2007). Unlike rheumatoid arthritis, osteoarthritis is not considered an autoimmune disease. *See* Tr. 191:8 to 193:2 (Test. of Dr. Arthur E. Brawer who provided expert testimony for petitioner) (describing the differences between rheumatoid arthritis and osteoarthritis). The "cervical spine" is that portion of the spine "pertaining to the neck." *Dorland's* at 339. The "lumbar spine" is that portion of the spine "pertaining to the loins, the parts of the sides of the back between the thorax and the pelvis." *Id.* at 1092. "Clinical" is defined as "founded on actual observation and treatment of patients [at the bedside]." *Id.* at 378. "Radiographic" is defined as "pertaining to or produced by radiography [or X-ray]." *Id.* at 1596.

[5]Non-alcoholic steatohepatitis is an inflammatory disease of the liver that occurs in people who drink little or no alcohol. *See Dorland's* at 1794.

[6]Antinuclear antibodies are "substances produced by the immune system that attack the body's own tissues." U.S. National Library of Medicine and National Institutes of Health, MedlinePlus, *Antinuclear Antibody Panel*, http://www.nlm.nih.gov/medlineplus/ency/article/003535.htm (updated Feb. 3, 2009).

On December 4, 2003, Ms. Campbell saw her primary care doctor, Dr. Thad Jackson. Entitlement Decision at *1. Ms. Campbell reported pain in both of her shoulders, hip, and upper and lower back, and severely restricted use of her left shoulder. *Id*.; R. Ex. 1 at 100024-25. Dr. Jackson noted that Ms. Campbell appeared depressed because her pain and loss of mobility prevented her from participating in activities she once enjoyed, such as hunting and fishing. Entitlement Decision at *1; R. Ex. 1 at 100024-25. Dr. Jackson recommended psychological counseling, which Ms. Campbell did not pursue, and water therapy. Entitlement Decision at *1. Ms. Campbell received the trivalent influenza and pneumonococcal vaccines during this visit. *Id*.[7]

On December 8, 2003, Ms. Campbell returned to Dr. Jackson's office. Entitlement Decision at *2. Ms. Campbell reported that "she was in her usual state of health until Sunday," December 7, 2003, when she was bumped by three teenagers while leaving church. Entitlement Decision at *2; R. Ex. 2 at 200100; Tr. at 117:5-8 (Brawer), 240:1-9 (Lightfoot). Dr. Jackson made a note in Ms. Campbell's medical records that this incident "was quite painful for her as she has had a history of chronic left upper shoulder pain." R. Ex. 2 at 200100. Ms. Campbell reported that within a few hours of the incident at church she began to experience pain in her left arm that radiated up to her left shoulder, and subsequently experienced similar pain in her right arm accompanied by difficulty swallowing and chest heaviness. Entitlement Decision at *2; R. Ex. 2 at 200100. Upon examination of Ms. Campbell's upper extremities, Dr. Jackson noted what appeared to be systemic swelling and warmth in both of Ms. Campbell's upper extremities and diminished grip strength. Entitlement Decision at *2. Dr. Jackson admitted Ms. Campbell to Grayling Mercy Hospital ("Mercy") on December 8, 2003 for further evaluation and medical testing. *See id.*

While admitted to Mercy, Ms. Campbell underwent orthopedic testing and evaluation. *See* Entitlement Decision at *2. Ms. Campbell had an MRI scan of her brain, which was normal, and one of her cervical spine, which showed some disc bulging at the C4-5 and C5-6 disc spaces. *Id.* X-rays of her lumbar spine showed some narrowing of disc space. *Id*. An orthopedist, Dr. Darius Divina, examined Ms. Campbell on December 9, 2003, and noted that her "left and right shoulders seem[ed] somewhat swollen and slightly warm to touch." R. Ex. 2 at 200110. Dr. Divina was unable to determine the cause of Ms. Campbell's pain, *see* Entitlement Decision at *2; however, Dr. Divina noted two conditions to "rule out," (i) "acute inflammatory response to vaccine" and (ii) "septic bursitis." R. Ex. 2 at 200109.[8]

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[7]Neither party in this case has alleged that the pneumococcal vaccine Ms. Campbell received on December 4, 2003 caused the onset of her rheumatoid arthritis. *See* Entitlement Decision at *6. Ms. Campbell received the adult version of the pneumococcal vaccine, called Pneumovax 23™, which is not listed on the Vaccine Injury Table. *Id*. at *1 (citing 42 C.F.R. § 100.3(a)(Table, Provision XIII); 66 Fed. Reg. 28166 (May 22, 2001)).

[8]Septic bursitis is "inflammation of a bursa that [is] caused by infection, usually the result of bacterial inoculation due to trauma." *Dorland's* at 269. A bursa is "a sac or saclike cavity

Also during her stay at Mercy, Ms. Campbell underwent ANA and rheumatoid factor testing, the results of which were a positive ANA test and a rheumatoid factor of 20. Entitlement Decision at *2; R. Ex. 2 at 200092-94.[9] Ms. Campbell's pain decreased during her stay at Mercy, and she was discharged on December 10, 2003. Entitlement Decision at *2. At the time of her discharge, Ms. Campbell's diagnosis was "[a]cute bilateral upper extremity inflammatory arthritis" of unknown cause. *Id*.

According to Ms. Campbell, she continued to experience pain and swelling in her upper extremities after having been discharged from the hospital, and on December 12, 2003, Ms. Campbell visited the emergency room at Mercy, reporting pain in her extremities, including her left foot. Entitlement Decision at *2. The emergency room doctor who examined Ms. Campbell had the impression that her pain was due to inflammatory arthritis. *Id*. Neither the doctor's report nor his examination notes mention whether Ms. Campbell had swelling in her joints at the time of her emergency room visit. *Id*. The emergency room doctor prescribed Dilaudid for Ms. Campbell's pain and arranged a wheelchair for her. *Id*.; R. Ex. 2 at 200152. Ms. Campbell was not admitted to the hospital on December 12, 2003. Entitlement Decision at *2.

Ms. Campbell returned to Dr. Jackson, her primary care doctor, about one week later, on December 19, 2003. Entitlement Decision at *2; R. Ex. 1 at 100023. Ms. Campbell "reported that she had developed weakness in her legs such that she could stand for only ten seconds [at a time] and could not walk." Entitlement Decision at *2. With regard to her upper extremities, Ms. Campbell reported that her "joint symptoms, particularly [in] the upper extremities, [were] 100% better." *Id*. Dr. Jackson noted that Ms. Campbell had "some joint tenderness," but did not note any joint swelling. *Id.* Dr. Jackson's impressions from his examination of Ms. Campbell on December 19, 2003, as quoted in the Entitlement Decision, were as follows:

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 [ten] 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[al] disease versus possible reactivity due to her previous influenza vaccine.

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filled with a viscid fluid and situated at places in the tissues at which friction would otherwise develop." *Id*. at 266.

[9]According to Dr. Robert Lightfoot, an expert who testified on behalf of the government, a rheumatoid factor of 20 is normal or "negative" and a rheumatoid factor of 50 or 80 or higher is abnormal or "positive." Tr. 413:21-25 (Lightfoot).

*Id*. at *3.[10] Upon consultation with Dr. Jay Jones of Physical Medicine and Rehab and Dr. Diane Donley of Neurology, both at Munson Medical Center ("Munson"), Dr. Jackson admitted Ms. Campbell to Munson for neurological and rheumatological evaluation. *Id*.; R. Ex. 1 at 100022.

During her stay at Munson, Ms. Campbell underwent neurological and rheumatological testing. Entitlement Decision at *3. Neuromuscular testing revealed no polyneuropathy, myopathy, or any other major defect or neuromuscular junction disorder. *See* R. Ex. 8 at 8-15.[11] Rheumatological testing showed "[p]ositive serologies, polyarthritis and weakness in a woman status post influenza and Pneumovax vaccinations." Entitlement Decision at *3.[12] The results of Ms. Campbell's rheumatological testing prompted Dr. Donley to contact Dr. Karen Gilhooly, a rheumatologist, for a consultation. *Id*.; *see* R. Ex. 8 at 8-12. On December 19, 2003, Dr. Gilhooly examined Ms. Campbell and reviewed her medical history. Entitlement Decision at *3. Dr. Gilhooly found tenderness along Ms. Campbell's joints in her fingers and hands and in her hip, knee, and ankles at the extreme range of motion, but did not find synovitis (inflammation of the joint lining). *Id*.; *see Dorland's* at 1879. Dr. Gilhooly's overall impressions of Ms. Campbell's condition, as quoted in the Entitlement Decision, were as follows:

1. Post vaccination reactive arthritis. question myalgias weakness in a woman with positive seriologies, ANA, [and] rheumatoid factor . . .[13]

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.

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[10]Arthralgia is "pain in a joint," *Dorland's* at 152, while myalgia is "pain in a muscle or muscles." *Dorland*'s at 1233.

[11]Polyneuropathy is "a functional disturbance or pathological change in ['several peripheral nerves simultaneously']." *Dorland's* at 1287, 1513. Myopathy is "any disease of a muscle." *Dorland's* at 1243.

[12]Serologies indicate "the presence of antibodies against a microorganism." U.S. National Library of Medicine and National Institutes of Health, MedlinePlus, *Serology*, http://www.nlm.nih.gov/medlineplus/ency/article/003511.htm (updated Oct. 15, 2007).

[13]At the hearing, Dr. Lightfoot opined that Dr. Gilhooly, who dictated this note, intended the word "question" to be a question mark immediately following "post vaccination reactive arthritis," rather than a verb preceding "myalgias [and] weakness." *See* Tr. 415:23 to 416:25 (Lightfoot).

Entitlement Decision at *3 (quoting R. Ex. 3 at 300026). Dr. Gilhooly recommended "watchful waiting," which included, among other things, repeat testing of Ms. Campbell's rheumatic serologies. *Id*.

Ms. Campbell was also evaluated by Dr. Richard D. Ball during her hospital admission on December 19, 2003. Entitlement Decision at *3.[14] Dr. Ball determined Ms. Campbell did not have a polyneuropathy and subsequently ruled out nervous system disorders such as Guillain-Barré syndrome and chronic inflammatory demyelinating polyneuropathy as the cause of Ms. Campbell's symptoms. *Id*. Dr. Ball agreed with Dr. Gilhooly's opinion that Ms. Campbell had a "rheumatological problem, probably precipitated/exacerbated by her recent Pneumovax/flu vaccines." *Id*. In accord with the opinions of Drs. Gilhooly and Ball, Ms. Campbell was discharged from Munson the same day she was admitted, December 19, 2003. *Id*. The discharge report stated "[Dr. Ball and Dr. Gilhooly] 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.'" *Id*. (quoting R. Ex. 3 at 300018).

On December 24, 2003, Ms. Campbell returned to Dr. Jackson's office, at which time he reviewed some of the laboratory work from her hospitalization on December 19, 2003 and examined her extremities. Entitlement Decision at *4. Dr. Jackson's examination revealed "[n]o active tenosynovitis [(synovitus involving a tendon)] [or] edema [('presence of abnormally large amounts of fluid in the intercellular tissue spaces of the body')]." *Id*.; *Dorland's* at 600, 1905. Dr. Jackson's impression at that time was that Ms. Campbell had "inflammatory arthritis, etiology indeterminate." Entitlement Decision at *4.

On January 13, 2004, Ms. Campbell had a further appointment with Dr. Gilhooly, the purpose of which was described by Dr. Gilhooly as "follow-up regarding question post-vaccination immune phenomenon versus triggering of primary autoimmune phenomenon such as lupus, Sjogren's [syndrome], or rheumatoid." Entitlement Decision at *4; R. Ex. 3 at 300048. Ms. Campbell reported she had "[n]o swelling, [but] some warmth [and] stiffness in the morning [for] a half hour." *Id*. Dr. Gilhooly noted that the physical examination showed "passive range of motion about the joints, slight tenderness at the extremes of right wrist extension [and] left elbow extension." *Id*. Dr. Gilhooly did not note any swelling. *Id*. Dr. Gilhooly's impressions at this time were "[q]uestion autoimmune disease, undifferentiated . . . Keep in mind Sjögren's, lupus versus immune phenomenon simply triggered by the immunization that will gradually resolve." *Id*.

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[14]Although the Entitlement Decision states that Dr. Ball's specialty "is not apparent," Entitlement Decision at *3, Dr. Ball's medical determinations regarding Ms. Campbell's condition suggest that Dr. Ball practices as a neurologist. *See id.* ("Dr. Ball determined that Ms. Campbell did not have a polyneuropathy of any type.").

Ms. Campbell saw Dr. Gilhooly again in February 2004. Entitlement Decision at *4. Ms. Campbell reported that she continued to have bilateral pain and stiffness at her metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal joints and "[v]ariable morning stiffness" that worsens as the day goes on. *Id*. These joints are located in the hands, feet, and fingers and toes, respectively. *Id*. at *4 n.1 (citation omitted). Ms. Campbell reported that her symptoms became "[w]orse with weight bearing and gripping activities." *Id*. at *4. Again, Ms. Campbell did not report any swelling. *Id.* Dr. Gilhooly's physical examination of Ms. Campbell showed "[t]enderness to palpation of the [metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal joints] as well as to squeeze but no active synovitus." *Id*. Dr. Gilhooly's impression of Ms. Campbell's condition as of the date of this visit was "[q]uestion inflammatory arthritis; question forme fruste of lupus triggered by immunization." *Id*.

Ms. Campbell was examined by Dr. Jackson on March 11, 2004. Entitlement Decision at *4. The physical examination showed "[n]o edema." *Id*. At that time, Dr. Jackson noted that Ms. Campbell "had difficulty with an inflammatory arthritis after she received a flu vaccine." R. Ex. 1 at 100020. His impressions were "[g]eneralized arthralgias and myalgias with working diagnosis of post-inflammatory arthritis status post flu injection." Entitlement Decision at *4. Dr. Jackson also included an adverse reaction to the influenza vaccine in Ms. Campbell's allergy list. R. Ex. 1 at 100015.

Ms. Campbell was seen by Dr. Gilhooly on April 23, 2004. Entitlement Decision at *4. Dr. Gilhooly's typed office notes from this visit state that the purpose of the visit was to "follow up for undifferentiated connective tissue disease, ANA positive, rheumatoid factor negative, and hypergammaglobulinemia." *Id*.[15] Dr. Gilhooly's physical examination of Ms. Campbell showed "tenosynovitis over extensor right wrist [and] [metacarpophalangeals], slight decreased fist formation . . .[, and] trace synovitis perhaps over the ankles." *Id.* Dr. Gilhooly postulated that Ms. Campbell could have "Sjogren's syndrome versus undifferentiated connective tissue disease." *Id*. During this visit, Dr. Gilhooly prescribed Plaquenil. *Id*.

Ms. Campbell's next follow-up visit with Dr. Gilhooly occurred on June 11, 2004. Entitlement Decision at *5. Dr. Gilhooly noted that Ms. Campbell was being seen for "inflammatory arthritis, positive ANA, status post pneumovax." *Id*. Ms. Campbell reported that the Plaquenil Dr. Gilhooly prescribed on April 23, 2003 "was helping to some extent." *Id*. Dr. Gilhooly decided to continue prescribing Plaquenil. *Id*. The physical examination revealed that Ms. Campbell's proximal interphalangeal and distal interphalangeal joints were puffy and her metacarpophalangeal joints and wrists were tender at the extremes, but that there was no active synovitis. *Id*. For the first time, Ms. Campbell reported scalp psoriasis. *Id*. Dr. Gilhooly's physical examination of Ms. Campbell's scalp showed "psoriasiform plaque in

[15]Hypergammaglobulinemia is "an excess of gamma globulins in the blood, seen frequently in chronic infectious diseases." *Dorland's* at 901.

the scalp." *Id.*[16] Dr. Gilhooly diagnosed this condition as "probable psoriatic arthritis." *Id.*[17] Dr. Gilhooly asked Ms. Campbell to return in approximately four months. *Id.*

Ms. Campbell's next appointment with Dr. Gilhooly was on September 21, 2004 for a follow up for "PA" (psoriatic arthritis) and "FM" (fibromyalgia). Entitlement Decision at *5; *see also id*. (citing Neil M. Davis, *Medical Abbreviations* 148 (12th ed. 2005)).[18] Dr. Gilhooly again diagnosed Ms. Campbell with psoriatic arthritis and asked her to return for a follow-up appointment, this time in six weeks. *Id.* However, Dr. Gilhooly died in an automobile accident sometime between September 21, 2004 and November 12, 2004. *Id.*

After Dr. Gilhooly's death, Ms. Campbell began to visit the Harbor Arthritis Center for treatment. Entitlement Decision at *5. Ms. Campbell saw Jane Denay, a Certified Family Nurse Practitioner, on January 13, 2005. *Id.*; *see id*. at n.2. Ms. Denay reported "no evidence of an inflammatory arthropathy[,] . . . [and] suggested that Ms. Campbell might have fibromyalgia." *Id*. (internal quotation marks omitted).[19] Ms. Campbell continued to go to the Harbor Arthritis Center for treatment until September 2005. *See* R. Ex. 3 at 300001.

Ms. Campbell moved to Reno, Nevada, at which time she began to see Dr. Teresa Bachman, a rheumatologist referred to her by Ms. Denay. *See* R. Ex. 4 at 400005-07. Ms. Campbell was eventually diagnosed with rheumatoid arthritis, a diagnosis the accuracy of which neither party disputes. Entitlement Decision at *1.

Ms. Campbell filed a petition for vaccine injury compensation on June 28, 2007 and an amended petition on August 31, 2007. Entitlement Decision at *5. By agreement of the parties, hearings were held on October 21, 2008, in New York, New York and on January 15, 2009, in Washington, D.C., "limited to determining whether Ms. Campbell suffered an adverse reaction to the flu vaccine." *Id*. at *6. During the hearing, Ms. Campbell's expert, Dr. Brawer, offered six

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[16]Psoriasis is "any of a group of common chronic, squamous dermatoses with variable symptoms and courses; some are inherited." *Dorland's* at 1570. "Plaque psoriasis" is "the most common type of psoriasis, in which lesions are in round plaques with distinct borders." *Id.* at 1571.

[17]Psoriatic arthritis is "a syndrome of psoriasis in association with arthritis; rheumatoid factor is usually not present in the serum of affected individuals." *Dorland's* at 152.

[18]Fibromyalgia is "pain and stiffness in the muscles and joints that either is diffuse or has multiple trigger points." *Dorland's* at 711. At the hearing, Dr. Brawer opined that fibromyalgia was a "gross oversimplification" of Ms. Campbell's diagnosis because in his experience, patients can simultaneously fulfill the criteria for fibromyalgia and rheumatoid arthritis. Tr. 75:4-12 (Brawer).

[19]Arthropathy is "any joint disease." *Dorland's* at 160.

separate theories that could explain how receipt of influenza vaccine could cause onset of rheumatoid arthritis. Tr. 17:17 to 30:25, 38:7 to 55:23 (Brawer). Nonetheless, Dr. Brawer focused on the "primary theory," Tr. 26:19 (Brawer), that "antigens of infectious agents can cross-react with self-antigens present on immunocompetent cells, thereby triggering inflammatory systemic connective tissue diseases such as Rheumatoid Arthritis." R. Ex. 11 at 11-1. Dr. Brawer drew support for this theory from case reports of patients developing rheumatoid arthritis after receiving a vaccination. *See* Entitlement Decision at *10 (citing R. Exs. 23, 24, 25, 27, 32, 33). Dr. Lightfoot discounted the case reports because they did not posit a causal connection between the vaccine and rheumatoid arthritis. *See*, *e.g.*, Tr. 310:18-22 (Lightfoot). He indicated that new cases of rheumatoid arthritis are relatively common, averaging approximately 332 new cases per day in the United States in 2006, Tr. 265:17-18, 424:24-25 (Lightfoot), and administration of trivalent influenza vaccine is also common, occurring with 32.3% of the population that could have been vaccinated. Tr. 425:6-13 (Lightfoot). In his view, some people who develop rheumatoid arthritis will have received an influenza vaccination within the prior 30 days, purely by chance. Tr. 423:16 to 427:12 (Lightfoot).

The special master rejected Dr. Brawer's medical explanation, finding that Dr. Brawer did not explain very well his theories "for how the influenza vaccine could cause rheumatoid arthritis" or "plac[e] them into the context of Ms. Campbell's case." Entitlement Decision at *9. The special master opined that the "medical theory[, even if established as reliable,] must focus on the specific vaccine and the specific injury at issue." *Id*. Applying this principle, the special master concluded that Dr. Brawer's failure to "show[] some similarity in molecular structure between a portion of the vaccine and a portion of a relevant body part . . . lessens the reliability of his opinion that molecular mimicry explains the connection between the influenza vaccine and rheumatoid arthritis." *Id*. at *10. The special master also gave little or no consideration to the case reports submitted by Ms. Campbell of patients who developed rheumatoid arthritis after having received a vaccination. *See id*. at *10-11. Based on the testimony of respondent's expert, Dr. Lightfoot, that purely by chance "184 people [per] day . . . are getting rheumatoid arthritis and [influenza] vaccines," Tr. 426:19-21 (Lightfoot), the special master concluded that "[the case reports] present[ed] a chronological picture only." Entitlement Decision at *11.

The special master also discounted Dr. Brawer's opinion that Ms. Campbell's rheumatoid arthritis began within two to fourteen days of receiving the influenza vaccine. Entitlement Decision at *11. Specifically, the special master found that "Ms. Campbell was not experiencing swelling in her joints – the hallmark of rheumatoid arthritis – within [two to fourteen days]" of receiving the vaccination. *Id*. at *13. "One simple reason" that the special master gave in support of his finding was "that Dr. Lightfoot did not agree with Dr. Brawer" and "Dr. Lightfoot's opinion [was] more persuasive." *Id*. at *11. Notwithstanding Dr. Jackson's diagnosis on December 10, 2003 of "[a]cute bilateral upper extremity inflammatory arthritis," the special master afforded it only "some consideration." *Id*. at *12. In the special master's view, a series of factors "raise[d] questions about the accuracy of Dr. Jackson's December 10, 2003 diagnosis," *viz*., (i) "Dr. Jackson anticipated that a consultation with a rheumatologist might be

necessary to provide a more complete diagnosis;" (ii) "Dr. Jackson did not provide a basis for his conclusion that Ms. Campbell suffered from inflammatory arthritis;" (iii) "the report suggests that Ms. Campbell had swelling throughout her upper arms, not just in [her] joints" and "[t]his type of swelling is not consistent with the usual presentation of rheumatoid arthritis;" and (iv) "Dr. Jackson may have also considered that Ms. Campbell's test for ANA was positive . . . [and] a positive ANA [test] is not diagnostic for rheumatoid arthritis." *Id*.

Overall, the special master rejected "the statements of Ms. Campbell's treating physicians" as proof of causation because they were "not *clear* statements that the flu vaccine caused [her] to develop rheumatoid arthritis." Entitlement Decision at *14 (emphasis added). The special master found that "[Dr. Gilhooly's] records [were] ambiguous in that they mention the flu vaccine and the pneumonococcal vaccine" with respect to a possible adverse reaction, and "the statements of Ms. Campbell's treating doctors . . . sometimes did not say that the vaccination 'caused' a problem," but instead they merely "presented a chronology." *Id*. The special master recognized that Dr. Jackson's report of November 12, 2004, which stated that Ms. Campbell was "positive for severe adverse reaction to influenza vaccine last year requiring hospitalization," "more clearly support[ed] a finding of entitlement," but the special master favored Dr. Jackson's earlier report of December 19, 2003, which merely stated that a vaccine reaction was "possible." *Id*. at *15. The special master also commented that "Dr. Jackson[, who did not testify at the hearing,] did not explain [in the records] why his opinion evolved." *Id*. at *15.

## STANDARDS FOR REVIEW

Under the Vaccine Act, when reviewing a decision of a special master on a motion for review, the court has jurisdiction to "undertake a review of the record of the proceedings" and may take any of the following actions:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
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> (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2); *see also* RCFC, App. B, Rule 27.[20] The Vaccine Act requires this

[20]Prior to 1989, the judges on this court had the option of either "adopt[ing] the findings of the special master as [their] own judgment, or mak[ing] a de novo determination of any matter and issu[ing] [their] judgment accordingly." Randall B. Keiser, *Deja Vu All Over Again? The*

court to analyze conclusions of law made by a special master to determine whether they are "not in accordance with law." 42 U.S.C. § 300aa-12(e)(2). Factual findings by a special master may be set aside if they are found to be arbitrary or capricious or if a special master has abused his or her discretion in making such findings. *See id*. The Federal Circuit has commented that, "reversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." *Lampe v. Secretary of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal quotation marks omitted) (citing *Hines ex rel. Sevier v. Secretary of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)). While "it is not . . . the role of [the reviewing] court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence . . . [,] [or to] examine the probative value of the evidence or the credibility of the witnesses," *Lampe*, 219 F.3d at 1360 (quoting *Munn v. Secretary of Health & Human Servs.*, 970 F.2d 863, 871 (Fed. Cir. 1992)), a special master may not "frame her rejection of [a petitioner's] theory of causation under the rubric of a 'credibility' determination," *Andreu v. Secretary of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009), nor may a special master "cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." *Id*.

In adopting the Vaccine Act, Congress sought to "establish a [f]ederal 'no-fault' compensation program under which awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity." H.R. Rep. No. 99-908, at 3 (2d Sess. 1986), *reprinted in* 1986 U.S.C.C.A.N. 6334, 6334. To pursue its goals of a generous remedial program, Congress established a Vaccine Injury Table.[21] When a petitioner "[b]ring[s] [a] case within the timetable and specifications of a Table [i]njury[,] . . . the statute does the heavy lifting – causation is conclusively presumed." *Hodges v. Secretary of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). For a petitioner to be able to avail himself or herself of the Vaccine Injury Table, the claimant must "establish that [he or she] received a listed vaccine and experiences such symptoms or injuries within the specified timeframes." *de Bazan*, 539 F.3d at 1351.

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*National Childhood Vaccine Injury Compensation Act of 1986*, 47 Food & Drug L.J. 15, 23 (1992). The statute was amended in 1989 to eliminate the ability of the judges on this court to review any portion of the special master's decision de novo. *See* Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6601(h), 103 Stat. 2106, 2289 (codified at 42 U.S.C. § 300aa-12(e)).

[21]The initial Vaccine Injury Table was published at 42 U.S.C. § 300aa-14(a). The Table can be, and has been, revised by the Secretary of Health and Human Services acting pursuant to notice-and-comment rulemaking under the authority of 42 U.S.C. § 300aa-14(c). The current version of the Vaccine Injury Table, as amended, is set out at 42 C.F.R. § 100.3. *See supra*, at 2 n.2.

However, if a petitioner is unable to bring a claim that falls within the scope of the Table,[22] the individual is required to prove causation in fact by a preponderance of the evidence. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), -13(a)(1)(A); *Althen v. Secretary of Heath & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The Federal Circuit has held that the causation-in-fact standard employed in off-Table vaccine cases "is the same as 'legal cause' in the general torts context." *de Bazan*, 539 F.3d at 1351 (citing *Shyface v. Secretary of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)).

In *Althen*, the Federal Circuit clarified that to prove causation in fact, a petitioner must show, by preponderant evidence, the following:

> (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*, 418 F.3d at 1278.[23] Once the petitioner has made a prima facie case for entitlement, "the burden shifts to the government to prove by a preponderance of the evidence that the petitioner's injury is due to factors unrelated to the . . . vaccine." *de Bazan*, 539 F.3d at 1352 (internal quotation marks omitted) (citation omitted). The Federal Circuit "has interpreted the 'preponderance of the evidence' standard . . . as one of proof by a simple preponderance, of 'more probable than not' causation." *Althen*, 418 F.3d at 1279 (citation omitted). "'Close calls

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[22]As noted, the inclusion of trivalent influenza vaccine on the Table is not accompanied by any listing of Table injuries or any time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration. *See supra*, at 2 n.2. Thus, no claims related to administration of trivalent influenza vaccine can be said to fall within the Table, and all such claims necessarily must be for off-Table injuries.

[23]With regard to this test, the Federal Circuit also stated in *Althen* that "[a] persuasive medical theory is demonstrated by proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury, the logical sequence being supported by reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278 (internal quotation marks omitted) (citation omitted); *see also Capizzano v. Secretary of Health & Human Servs.*, 440 F.3d 1317, 1324-27 (Fed. Cir. 2006) (applying the *Althen* test).

"The 'proximate temporal relationship' standard requires 'preponderant proof that the onset of symptoms occurred within the timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *Rotoli v. Secretary of Health & Human Servs.*, __ Fed. Cl. __, __ n.5, 2009 WL 2868840, at *3 n.5 (2009) (quoting *de Bazan*, 539 F.3d at 1352).

regarding causation are resolved in favor of injured claimants.'" *Andreu*, 569 F.3d at 1378 (quoting *Capizzano*, 440 F.3d at 1325-26).

The preponderance of the evidence standard does not require "scientific certainty." *Bunting v. Secretary of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). "[D]etermination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain." *Knudsen ex rel. Knudsen v. Secretary of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994) (citations omitted). "[A]scertaining precisely how and why . . . vaccines sometimes destroy the health and lives of certain [individuals] while safely immunizing most others . . . is for scientists, engineers, and doctors working in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies." *Id*. at 549. The absence of "a link between a vaccine and a particular injury," or "that the state of medical knowledge regarding a causal link . . . can be characterized as 'controversial,'" "will not bar recovery, because 'the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Rotoli*, __ Fed. Cl. at __, 2009 WL 2868840, at *4 (quoting *Althen*, 418 F.3d at 1280); *id.* at *4 n.7. Thus, a finding of causation in fact in vaccine cases can be "based on epidemiological evidence and the clinical picture . . . without detailed medical and scientific exposition on the biological mechanisms." *Knudsen*, 35 F.3d at 549.

"[P]ursuant to 42 U.S.C. § 300aa-13(a)(1), a finding of preponderant evidence of causation[]in[]fact must be substantiated by medical records *or* by medical opinion." *Rotoli*, __ Fed. Cl. at __, 2009 WL 2868840, at *4 (citing *Althen*, 418 F.3d at 1279). A finding of preponderant evidence of causation in fact "may be based on a reliable medical opinion alone," *id.* (citing *Althen*, 418 F.3d at 1280), but where medical literature or epidemiological evidence "'is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury.'" *Id*. at *4 n.9 (quoting *Andreu*, 569 F.3d at 1379-80, and *citing Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593-97 (1993) for the proposition that "one factor for assessing the reliability of expert testimony is whether the theory espoused enjoys general acceptance within a relevant scientific community").

## ANALYSIS

One of the confounding aspects of this case is that it involves a diagnosis of rheumatoid arthritis, which frequently is classified as an autoimmune disease, whereas other forms of arthritis are not considered autoimmune diseases. *See supra*, at 3 n.4.[24] Moreover rheumatoid arthritis usually cannot be diagnosed immediately but rather requires a period of time for testing

[24]Other somewhat related autoimmune diseases or conditions include lupus, scleroderma, and Sjögren's syndrome. *See* Entitlement Decision at *4 (listing autoimmune conditions cited by Dr. Gilhooly in her notes after a visit by Ms. Campbell on January 13, 2004) (quoted *supra*, at 8); *Dorland's* at 1093, 1705, 1871.

and observation before a confident diagnosis can be made. *See infra*, at 22-24 & nn.34 & 36. Not surprisingly, then, especially early in Ms. Campbell's medical travails with arthritis, the record contains differing references by Ms. Campbell's treating physicians to the type of arthritic disease which properly described her condition.

### A. *Rheumatoid Arthritis*

In very broad terms, rheumatoid arthritis is "a chronic systemic disease primarily of the joints, usually polyarticular [('affecting many joints')], marked by inflammatory changes in the synovial membranes and articular structures and by muscle atrophy and rarefaction [('diminution in density and weight')] of the bones. In late stages deformity and ankylosis [('immobility and consolidation of a joint')] develop. The cause is unknown, but autoimmune mechanisms and virus infection have been postulated." *Dorland's* at 94, 152, 159, 1509, 1617. The parties' experts appeared to be in general agreement with the following seven criteria for the classification of rheumatoid arthritis as developed by the American College of Rheumatology (formerly the American Rheumatology Association): (1) "[m]orning stiffness in and around the joints, lasting at least [one] hour before maximal improvement;" (2) "[a]t least [three] joint areas simultaneously have had soft tissue swelling or fluid;" (3) at least one of the swollen joint areas is in a wrist or hand; (4) symmetry of the arthritis; (5) "rheumatoid nodules;"[25] (6) a positive "serum rheumatoid factor;"[26] and (7) erosions of the joints[27] visible by X-ray. American College of Rheumatology, *1987 Criteria for the Classification of Acute Arthritis of Rheumatoid Arthritis*, http://www.rheumatology.org/publications/classification/ra/ra.asp ("1987 Criteria"); *see* Tr. 61:25 to 62:22 (Brawer), 270:5 to 272:10 (Lightfoot).[28] The peak age of onset of rheumatoid

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[25]Dr. Lightfoot described "rheumatoid nodules" as "small inflammatory nodules that can occur over pressure points, typically [in] the elbow." Tr. 272:4-6 (Lightfoot).

[26]"A rheumatoid factor test measures the amount of . . . autoantibodies - proteins produced by [the] immune system that can attack healthy tissue in [the] body" - in the blood. Mayo Clinic, *Rheumatoid Factor Definition*, http://www.mayoclinic.com/health/rheumatoid-factor/MY00241.

[27]According to Dr. Lightfoot, joint erosions are the result of "inflammatory tissue in the joint burrow[ing] in[to] [the joint] like a tumor and caus[ing] little caves in the joint structure." Tr. 272:7-10 (Lightfoot).

[28]The following annotation appears beneath the list of criteria for the classification of rheumatoid arthritis published by the American College of Rheumatology: "For classification purposes, a patient shall be said to have rheumatoid arthritis if he [or] she has satisfied at least [four] [of] these [seven] criteria. Criteria 1 through 4 must have been present for at least [six] weeks." *1987 Criteria; see* Tr:115:21-24 (Brawer) (agreeing that "in order to have a diagnosis of rheumatoid arthritis under those [criteria] you have to [meet] at least four out of seven [criteria]"); *see also* Tr. 62:17-22 (Brawer) ("[W]hen you have pain and swelling in small and

arthritis is in the mid to late fifties for women and at about seventy for men. Tr. 235:3-6 (Lightfoot).

Arthritis literally means joint inflamation, *Dorland*'s at 152, and encompasses over 100 different recognized conditions, many of which, such as osteoarthritis and gout, do not implicate an autoimmune cause. *See*, *e.g.*, *supra*, at 3 n.4. Of relevance to this case, acute arthritis is "marked by pain, heat, redness, and swelling, due to inflamation, infection, or trauma," *Dorland's* at 152, and reactive arthritis is "arthritis after an infection." *Id*. Both of these conditions may well be transient. *See*, *e.g.*, *supra*, at 6 (quoting Dr. Gilhooly's initial impressions of Ms. Campbell's condition).

The parties' experts agreed that Ms. Campbell had rheumatoid arthritis at the time of the hearing and that the medical records submitted to the special master as exhibits accurately described her condition. Entitlement Decision at *1. The parties' experts disagreed, however, as to what caused the onset of Ms. Campbell's rheumatoid arthritis and when it occurred. *Id.* Petitioner's expert, Dr. Brawer, stated that "the vaccine directly initiated the onset of [Ms. Campbell's] rheumatoid arthritis," Tr. at 57:9-10 (Brawer), which Dr. Brawer believed "began on December 6, 2003." Tr. at 118:2 (Brawer). Respondent's expert, Dr. Lightfoot, disagreed, opining that "only live or attenuated live vaccines[, which the influenza vaccine is not,] are capable of causing chronic arthritis," Tr. 367:10-19 (Lightfoot), and that it is impossible to determine when the onset of Ms. Campbell's rheumatoid arthritis occurred. Tr. 242:1-4 (Lightfoot).

### B. *The Special Master's Credibility Determination*

Both Dr. Brawer and Dr. Lightfoot were experienced rheumatolologists who endeavored to help the special master analyze the various diagnoses provided by Ms. Campbell's treating physicians and to explain the different forms of arthritis. Dr. Brawer graduated from Boston University's School of Medicine. After completing an internship and a residency, Dr. Brawer spent two years completing an arthritis fellowship at Boston University Medical Center. He went into private practice in 1976 and has seen approximately 15,000 new patients in that capacity and through a free arthritis clinic of which Dr. Brawer is the director. Tr. 9:3-24, 14:16 to15:8 (Brawer). Dr. Brawer has been board certified in internal medicine and rheumatology since 1975 and 1976, respectively. Tr. 9:25 to 10:6 (Brawer). Dr. Brawer's academic and other professional appointments include the following: (1) Associate Clinical Professor of Medicine at Hahnemann University Hospital, Drexel University; (2) Assisting Clinical Professor of Medicine at Robert Wood Johnson Medical School; (3) Director of Rheumatology at Monmouth Medical Center; (4) Former Vice President and Former President of the New Jersey Rheumatology Association; and (5) fellow of the American College of Rheumatology. Tr. 10:10 to 11:3 (Brawer). Dr. Brawer has also authored and co-authored some 16 publications and one book on

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large joints symmetrically . . . [and] morning stiffness and fatigue for six to eight weeks or longer, you have rheumatoid arthritis until proven otherwise.").

various topics related to rheumatology. Tr. 11:6-17 (Brawer). Correspondingly, Dr. Lightfoot graduated from Vanderbilt's Medical School. After completing an internship, Dr. Lightfoot also spent two years completing rheumatology training, at Columbia Presbyterian Medical Center. Tr. 220:13-22 (Lightfoot). He then served two years in the military, returning to take an academic position first on the faculty at Columbia University and subsequently on the faculty at Cornell University Medical Center. Tr. 220:21 to 221:2 (Lightfoot). Thereafter, he shifted to the University of Wisconsin's Medical College in Milwaukee and then to the University of Kentucky. Tr. 221:3-9 (Lightfoot). Dr. Lightfoot has authored chapters in textbooks on immunopathology of rheumatoid disease and the treatment of rheumatoid arthritis, and he has written roughly 45 or 50 articles in peer-reviewed journals. Tr. 221:16-25 (Lightfoot). He was a fellow of the American College of Rheumatology and became a master of that college in 2004, shortly after he had semi-retired in 2003 from the University of Kentucky's Medical School. Tr. 221:8-9, 222:12-15 (Lightfoot). Before entering semi-retirement, Dr. Lightfoot saw approximately 1,000 patients a year, and currently sees roughly half that number. Tr. 225:14-21 (Lightfoot).

In this case, the special master based his decision to deny Ms. Campbell compensation in substantial part on his finding that Dr. Lightfoot was more credible than Dr. Brawer. *See* Entitlement Decision at *7. Because there was no genuine issue with regard to Dr. Brawer's candor or truthfulness, the special master ran afoul of the Federal Circuit's standards regarding the use of credibility determinations. In *Andreu*, the Federal Circuit held that "[w]hile considerable deference must be accorded to the credibility determinations of special masters, this does not mean that a special master can cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." *Andreu*, 569 F.3d at 1379 (citation omitted). The Federal Circuit clarified that "[a] trial court makes a credibility determination in order to assess the candor of a fact witness, not to evaluate whether an expert witness' medical theory is supported by the weight of the epidemiological evidence." *Id*. As in *Andreu* and *Rotoli*, the special master in this case "cloak[ed]" his rejection of Ms. Campbell's theory of causation in a credibility determination regarding Ms. Campbell's expert witness, Dr. Brawer. *See Rotoli*, __ Fed. Cl. at __, 2009 WL 2868840, at *5 (citing *Andreu*, 569 F.3d at 1379). Just as in *Rotoli*, petitioner's expert in this case, Dr. Brawer, was "a highly qualified *expert* witness whose extensive credentials [were] not in dispute." *Id*.

"[W]here a highly qualified expert such as [Dr. Brawer] presents a biologically plausible theory of causation in a vaccine case, the issue is not one of credibility." *Rotoli*, __ Fed. Cl. at __, 2009 WL 2868840, at *5 (citing *Andreu*, 569 F.3d at 1379). Yet, the special master's evaluation of Dr. Brawer's credibility permeated his analysis of Ms. Campbell's claim for compensation. Prior to analyzing whether Ms. Campbell established causation in fact, the special master provided a "general evaluation of the experts." Entitlement Decision at *7-8; *see also Rotoli*, __ Fed. Cl. at __, 2009 WL 2868840, at *6 (criticizing this same approach). The special master concluded that Dr. Lightfoot was more "persuasive" than Dr. Brawer based on the following factors: (i) Dr. Lightfoot had "more experience in rheumatology" than Dr. Brawer as well as a "sterling" reputation; (ii) Dr. Lightfoot's demeanor conveyed that he was receptive to

the court's inquires and "want[ed] to impart knowledge," whereas Dr. Brawer's demeanor was more like that of an "advocate;" (iii) Dr. Lightfoot, as compared to Dr. Brawer, has "participated in litigation[] relatively rarely" and "does not derive a significant portion of his income from working as an expert witness;" and (iv) Dr. Brawer's expert opinions have not withstood *Daubert* challenges on at least two occasions. Entitlement Decision at *7-8. At the conclusion of this evaluation, the special master stated that "[the factors that contributed] to the finding that Dr. Lightfoot was more persuasive than Dr. Brawer . . . underlie the analysis of the three factors from *Althen* [that follows]." *Id*. at *8.

Thereafter, the special master's "evaluation of the experts" informed his analysis of whether Ms. Campbell met her burden of proof under *Althen*. Specifically, the special master cited Dr. Brawer's credibility as a primary reason to find Ms. Campbell had not established "a proximate temporal relationship between vaccination and injury" under the third prong of *Althen*. Entitlement Decision at *11 (internal quotation marks omitted). And, by couching his rejection of Ms. Campbell's claim in terms of credibility, the special master expected his analysis of whether Ms. Campbell had established causation in fact to be "virtually not reviewable on appeal." *Id*. at *7 ("A decision about the persuasiveness of a witness is virtually not reviewable on appeal") (citing *Bradley v. Secretary of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) (upholding a special master's credibility determination regarding a non-expert witness).[29]

Despite the special master's attempt to insulate his decision from review by the incantation of magic words, the court finds that he erroneously relied on an assessment of Dr. Brawer's credibility as a basis for rejecting Dr. Brawer's testimony and concluding that Ms. Campbell had not met her burden to establish causation in fact. As stated *supra*, an evaluation of the credibility of an expert witness should be reserved for "assess[ing] the candor of a fact witness" and Dr. Brawer's candor is not in dispute. *Andreu*, 569 F.3d at 1379. Further, the special master's error has tainted his entire analysis of whether Ms. Campbell established causation in fact. Not only did the special master expressly base his finding that Ms. Campbell did not establish a proximate temporal relationship primarily on his evaluation of Dr. Brawer's credibility, *see* Entitlement Decision at *11, but, by the special master's own averment, his evaluation of the experts pervaded his analysis of the remaining factors under *Althen*. *See id.* at *8. In accord with *Andreu* and 42 U.S.C. § 300aa-12(e)(2)(B), the court finds that the special master improperly framed his rejection of Ms. Campbell's claim "under the rubric of a 'credibility' determination," and thereby sets aside the special master's findings as legal error. *Andreu*, 569 F.3d at 1379 (citation omitted); *Rotoli*, __ Fed. Cl. at __, 2009 WL 2868840, at *6.

[29]The same special master made the same assertion in the *Rotoli* cases. *See Rotoli*, __ Fed. Cl. at __, 2009 WL 2868840, at *6.

C. *Petitioner's Medical Theory*

Dr. Brawer's primary theory – that the molecular structure of a part or parts of the trivalent influenza vaccine resembled the structure of Ms. Campbell's synovial tissue or fluid because of her genomic makeup and engendered an autoimmune response[30] – was the subject of considerable expert testimony at trial. *See*, *e.g.*, Tr. 25:21 to 27:11 (Brawer), 389:18 to 394:14 (Lightfoot). In essence, the special master rejected this medical theory in favor of Dr. Lightfoot's postulate that the disease appeared "coincidentally" after the vaccination, relying on testimony by Dr. Lightfoot that compared the approximate number of new cases of rheumatoid arthritis diagnosed each day in the United States (332 new cases) to the approximate number of people who receive trivalent influenza vaccine each year (70 million). *See* Entitlement Decision at *11; Tr. 425:11-13 (Lightfoot).[31]

However, the special master also criticized Dr. Brawer for not connecting the medical theory more specifically with the administration of the vaccine and the injury. *See* Entitlement Decision at *9. Dr. Brawer acknowledged that the theory as applied to Ms. Campbell's circumstances had not been proven or disproven. *Id*. at *19. After having provided a detailed explanation of the theory, *see* Tr. 135:8 to 137:1 (Brawer), Dr. Brawer suggested that "the crux of it probably lies with your genetic makeup." Tr. 137:5-6 (Brawer).[32] In response to the special master's question of whether it was possible to test the segments of the killed virus strains present in the vaccine and the DNA sequencing of Ms. Campbell's synovial fluid, Tr. 193:14-20, Dr. Brawer first observed that the trivalent influenza vaccine usually "does not contain pieces of [viral] genetic material," but rather "usually contains the proteins that surround the genetic

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[30]This theory has on occasion been cryptically described by the somewhat vernacular term "molecular mimicry." *See e.g.*, Entitlement Decision at *9.

[31]The same statistical argument was made and rejected in *Capizzano*, relating to an association of the hepatitis B vaccine with rheumatoid arthritis. *See Capizzano*, 440 F.3d at 1326-27 (recognizing the fact that "statistically" there are "instances where individuals suffer an initial onset of rheumatoid arthritis shortly after receiving the vaccine, but not as the result of the vaccine;" however, that possibility does not prevent a finding that it is more likely than not that the vaccine caused the [rheumatoid arthritis]"). The statistical-coincidence argument is no more persuasive here than it was in *Capizzano*.

[32]Dr. Brawer indicated that

> if certain amino acid sequences of the protein of the arms of those Class 2 molecules [HLA Class 2 molecules present only on immunocompetent cells] bears some striking resemblance to the foreign protein that you're mounting the response against, then you may not shut the process off. It may continue unabated and you hence go from eradication of infection to persistence of inflamation.

Tr. 137:6-12 (Brawer).

material." Tr. 194:2-4 (Brawer). Dr. Brawer then provided a detailed exegesis of why such testing would not be possible:

> Now in reactive arthritis in certain situations you can find sequences of bacteria like e.coli in the joint itself, okay. In other words, you can find evidence of the exact infection in an intestinal tract now deposited in the joint[s] themselves. In occasional cases that's been described.
>
> And in the rheumatoid synovium to make things even more complicated, it's been shown that the B cells, the antibody-producing cells in that, that rheumatoid panus, that sponge there, actually if you look for certain antibodies, you can actually find some that are directed toward viruses.
>
> But the general – I think that those studies are unrewarding because the protein would usually not exist in the form it was administered in. The body would dismember it and present only certain pieces to the immune system.
>
> So it probably would not survive in its entirety to be found in the joint. And I don't think the amino acid sequences would be long enough to draw any conclusions.

Tr. 195:10 to 196:2 (Brawer).[33]

The special master reduced this explanation to the postulate that "this lack of testability" "shows a weakness and lack of reliability of [Dr. Brawer's] theory." Entitlement Decision at *10. This supporting conclusion by the special master was erroneous. As the Federal Circuit had explained in *Knudsen*, "to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." 35 F.3d at 549. Instead, "causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular [vaccinated person] without detailed medical and scientific exposition on the biological mechanisms." *Id*.

[33]Dr. Lightfoot considered the testability possibility in a different but not inconsistent framework, commenting that "[f]or decades rheumatologists have been looking for clues to the viral etiology of rheumatoid arthritis." Tr. 393:3-5 (Lightfoot). In that connection, he related the results of research efforts that tended to show merely that rheumatoid arthritis patients "have higher general antibody levels, gamma [globulin] levels, than the normal population." Tr. 393:22-23 (Lightfoot).

In fact, both epidemiological evidence and the clinical records of the treating physicians were presented on Ms. Campbell's behalf in this case.

The special master noted that the medical articles presented by Ms. Campbell were generally case reports, "primarily assert[ing] that a patient developed rheumatoid arthritis after receiving a vaccination." Entitlement Decision at *10. These case reports were discounted by the special master because they "present[ed] a chronological picture only" and they "cannot exclude the possibility that the disease developed coincidentally after the vaccination." *Id*. at *11. These observations by the special master about the case reports have some validity but they do not indicate that the case reports are deprived of evidentiary value in support of Ms. Campbell's medical theory as expounded by Dr. Brawer.

At the entitlement hearings, Dr. Lightfoot viewed the case reports along the lines later adopted by the special master, *see*, *e.g.*, Tr. 264:19-24, 376:15 to 378:25 (Lightfoot); *see also* 277:12-16 (Lightfoot) ("[A]lthough a temporal relationship between several vaccines and the occurrence of autoimmune disease has been suggested in many case reports, there is so far no conclusive evidence for a causal link.") (paraphrasing the conclusion of an article included in the record as R. Ex. C: Thierry Vial & Jacques Descotes, *Autoimmune Diseases and Vaccinations*, 14 Eur. J. Dermatol. 86 (2004)).

Respecting conclusive evidence or proof to a scientific standard, the gold standard would be a double-blind control, placebo-controlled study of drug verses placebo. *See* Tr. 355:10-14 (Lightfoot). That was not the standard Dr. Lightfoot employed however, nor did he believe a double-blind control study would be appropriate in the circumstances; rather, he would look to a case-controlled study to supply appropriate evidence of causation one way or the other. Tr. 355:14-19 (Lightfoot). Neither type of study was available.

However, any suggestion of a requirement for a study meeting scientific standards of proof was rejected by courts addressing the Vaccine Act some time ago. As the Federal Circuit said in *Bunting*, 931 F.2d at 873, "[t]he standard of proof required by the Act is simple preponderance of evidence; not scientific certainty." *See also Andreu*, 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) ("*Althen* makes clear that a claimant's theory of causation must be supported by a 'reputable medical or scientific explanation' (quoting *Althen*, 418 F.3d at 1278); "[m]edical literature and epidemiological evidence must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard.").

Accordingly, to the extent that the special master reached beyond his credibility findings to draw conclusions about the validity of the principal medical theory propounded on behalf of Ms. Campbell, he proceeded on erroneous grounds. Testing and proof of specific biological mechanisms are not required in a case of this type, nor do epidemiological studies need to satisfy the requirements for scientific certainty as to causation.

D. *The Treating Physicians' Diagnoses*

As addressed previously, the clinical records of Ms. Campbell's treating physicians were presented in aid of her efforts to establish entitlement to compensation under the Vaccine Program. The special master concluded that those records failed to establish that the influenza vaccination Ms. Campbell received on December 4, 2003 caused the onset of her rheumatoid arthritis. *See* Entitlement Decision at *11-15. The special master discounted the diagnoses of Ms. Campbell's treating physicians as ambiguous and drew every inference against petitioner.

In addressing the third prong of the *Althen* test, *i.e.*, whether Ms. Campbell established "a proximate temporal relationship between vaccination and injury," the special master afforded only "some consideration" to Dr. Jackson's diagnosis rendered on December 10, 2003, within a week of Ms. Campbell's vaccination, of "[a]cute bilateral upper extremity inflammatory arthritis." *Id*. at *12 (internal quotation marks and citations omitted); *see supra*, at 10. Applicable precedents indicate, however, that statements made by treating physicians in vaccine cases should be afforded more than "some consideration." Moreover, here the special master used that phrase as a prelude to rejecting Dr. Jackson's diagnosis and those of all of the other treating physicians.

The special master discounted Dr. Jackson's diagnosis of December 10, 2003 for reasons that included the fact that "Dr. Jackson did not prescribe any medications usually given to treat inflammatory arthritis." Entitlement Decision at *12. The special master also pointed to the fact that persons suffering from rheumatoid arthritis exhibit "chronic inflammation in their peripheral joints." Entitlement Decision at *12. The special master found that "Ms. Campbell presented little persuasive evidence that she was suffering from inflammation in her joints within two weeks after vaccination." *Id*. Additionally, in the special master's view, "Dr. Jackson did not provide a basis for his conclusion that Ms. Campbell suffered from inflammatory arthritis," *id*., although acknowledging that "he [*i.e.*, Dr. Jackson] may have considered that her upper extremities were swollen and filled with fluid" and "Ms. Campbell's test for ANA was positive." *Id*. The special master opined that "a positive ANA is not diagnostic for rheumatoid arthritis." *Id*. The special master also considered that "as a practical matter, favoring the reports of all treating physicians may be impossible" in this instance because Dr. Jackson had used the term "inflammatory arthritis" to describe Ms. Campbell's condition and the rheumatologist, Dr. Gilhooly, who subsequently treated Ms. Campbell, used the term "reactive arthritis." *Id*. at *12 n.8. The special master considered that this divergence showed "different conclusions," and thus "the persuasiveness of each report must be evaluated." *Id*. This analysis was erroneous. Both "inflammatory" or "acute" arthritis and "reactive" arthritis share many attributes, *see supra*, at 16, and on a preliminary diagnosis may not appear to be appreciably different. Indeed, as Dr. Lightfoot testified, wholly apart from differentiating "inflammatory" arthritis from "reactive" arthritis, "early on you couldn't tell reactive arthritis from rheumatoid arthritis, if the [rheumatoid arthritis] was starting in just a few joints. Tr. 319:19-21 (Lightfoot).

Still further, the special master drew what he termed "[a] reasonable inference" from Dr. Gilhooly's records "that because there was no synovitis at the time of Dr. Gilhooly's examination of Ms. Campbell [on December 19, 2003, two weeks after Ms. Campbell's vaccination], Dr. Gilhooly did not diagnose rheumatoid arthritis." Entitlement Decision at *13. The special master's inference was neither "reasonable" nor appropriate; both parties' experts agreed that it would have been impossible to diagnose Ms. Campbell with rheumatoid arthritis until at least six or eight weeks had elapsed since the vaccination. S*ee supra*, at 15-16 & n.28.[34] In this respect also, the special master explained that "the statements of Ms. Campbell's treating physicians are not clear statements that the flu vaccine caused Ms. Campbell to develop rheumatoid arthritis." Entitlement Decision at *14.[35] However, the early diagnoses were

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[34]As Dr. Lightfoot testified:

> I think as Dr. Brawer has indicated, it may take time to prove someone has rheumatoid arthritis. Very often, mild rheumatoid disease, you don't really know that's what it is until several months or maybe a year have gone by and all the other possibilities have fallen by the wayside, in retrospect you make the diagnosis.

Tr. 230:19-24 (Lightfoot); *see also* Tr.319:6-18 (Lightfoot).

In this respect, Dr. Gilhooly's initial diagnosis, made on December 19, 2003, two weeks after Ms. Campbell's vaccination, seems reasonably prescient. As she then said:

> 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.

R. Ex. 3 at 300026.

[35]None of Ms. Campbell's treating physicians testified at the entitlement hearings. Only one of the two principal treating physicians, Dr. Jackson, could have been called to testify because Dr. Gilhooly had tragically been killed in an automobile accident. This lack of direct testimony is not of evidentiary significance. As the Federal Circuit has observed:

> In most instances, however, it is both inadvisable and unnecessary to subpoena the testimony of treating physicians. It would not be in the public interest for the specter of a subpoena to provide physicians with a disincentive to treat a vaccine-injured patient or to cause them to be less than forthright in creating medical records assessing the relationship between a vaccine and a patient's injury. The submitted documentary evidence can, under most circumstances, provide adequate insight into the medical opinions of treating physicians, and there is little need to subject them to cross-examination in federal court.

*Andreu*, 569 F.3d at 1383 (citing *Cucuras v. Secretary of Health & Human Servs.*, 993 F.2d

medically appropriate for arthritis generally, a condition that Ms. Campbell had not presented prior to her vaccination, and absent an instance of "explosive" onset of rheumatoid arthritis,[36] the treating doctors would have required at least six or eight weeks of evaluation before determining that Ms. Campbell had rheumatoid arthritis. In short, the special master's finding that there was no temporal association between Ms. Campbell's rheumatoid arthritis and the administration of trivalent influenza vaccine cannot stand on this record. *See Capizzano*, 440 F.3d 1317, 1326 (diagnoses of treating physicians typically are "quite probative" because they are "likely to be in the best position to determine whether a 'logical sequence of cause and effect shows that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280); *see also Andreu*, 569 F.3d at 1381-82 (evaluating "clinical picture" provided by records of treating physicians).

**CONCLUSION**

For the stated reasons, petitioner's motion for review is GRANTED, the decision of the special master dated July 7, 2009, denying compensation is VACATED, and the case is REMANDED to the special master for further proceedings. Specifically, the court sets aside the findings of the special master although it makes no affirmative findings of its own.

It is so ORDERED.

s/ Charles F. Lettow
Charles F. Lettow
Judge

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1525, 1528 (Fed. Cir. 1993)).

[36]Dr. Lightfoot testified that there are

> occasional cases where rheumatoid arthritis comes on explosively, and every joint in the body is swollen, and the patient is unable to get out of bed. And they even run a fever, and a very profound onset.
>
> But it's characteristically not easy to date the onset.

Tr. 269:17-22 (Lightfoot). Manifestly, Ms. Campbell's onset of rheumatoid arthritis was not of the "explosive" type but rather of the more characteristic type.