In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

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EARLEEN BEAN-SASSER,	*	No. 13-326V
	*	Special Master Christian J. Moran
Petitioner,	*	
	*	Entitlement, hepatitis B vaccine,
v.	*	rheumatoid arthritis, onset
	*	
SECRETARY OF HEALTH	*	Filed: April 5, 2016
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
* *	*	

James R. Kneisler, Jr., San Angelo, TX, for petitioner;
Alexis B. Babcock, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION[1]

Earleen Bean-Sasser received a dose of the hepatitis B vaccine and then manifested symptoms of rheumatoid arthritis approximately 11 hours later. She alleges that the vaccination caused her rheumatoid arthritis and seeks compensation through the National Childhood Vaccine Injury Compensation Program, codified at 42 U.S.C. § 300aa−10 through 34 (2012).

To support her claim, Ms. Bean-Sasser presented the opinion of an immunologist, Ernest N. Charlesworth. The Secretary countered with an opinion from a rheumatologist, Robert W. Lightfoot, Jr. Dr. Lightfoot's extensive experience in treating rheumatoid arthritis is one reason for finding his opinion — that Ms. Bean-Sasser was probably already suffering from rheumatoid arthritis

[1] The E-Government Act, 44 § 3501 (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

before she was vaccinated — persuasive. This finding means that the hepatitis B vaccine did not cause her rheumatoid arthritis. Therefore, Ms. Bean-Sasser is not entitled to compensation.

Rheumatoid Arthritis

Rheumatoid arthritis ("RA") is a chronic inflammatory autoimmune disease "marked by a symmetric, peripheral polyarthritis." Exhibit 31.1 (Ankoor Shah & E. William St. Clair, Rheumatoid Arthritis, in Harrison's Principles of Internal Medicine (Dan L. Longo et al. eds., 18th ed. 2012)) at 2738. It is a common form of arthritis, which is systemic joint inflammation, and often leads to permanent joint damage and physical disabilities. RA may cause decreased motion, reduced strength, deterioration of the joints and soft tissues, and irreversible deformities. Id.; exhibit 33.5 (Daniel Aletaha et al., 2010 Rheumatoid Arthritis Classification Criteria, 62 Arthritis & Rheumatism 2569 (2010)) at 2570-71.

Overall, RA affects around one percent of the population with the disease being about twice as prevalent in women. Exhibit C (Sherine E. Gabriel et al., The Epidemiology of Rheumatoid Arthritis in Rochester, Minnesota, 1955-1985, 42 Arthritis & Rheumatism 415 (1999)) at 415; Tr. 113-14. The average age of a person when diagnosed with RA is at around 60 years old. Exhibit C (Gabriel) at 415; Tr. 122.

The pathogenesis of RA is not yet fully understood. Genetics and environmental factors are often implicated, either separately or in conjunction, in the development of RA. Some studies have suggested that genetic considerations can explain 60 percent of RA occurrences. However, it is more commonly accepted that genetic factors explain 10-25 percent of occurrences. Exhibit 31.1 (Shah) at 2741; Tr. 166.

Because genetics appear not to cause all cases of RA, doctors presume that environmental factors play a vital role in the development of RA. Tr. 168. Relevant environmental factors include cigarette smoking and bacterial or viral exposure. Exhibit 31.1 (Shah) at 2742. Cigarette smoking is considered "the dominant environmental factor," and can double a person's potential for developing RA. Exhibit 33.3 (D.L. Scott et al., Rheumatoid Arthritis, 376 Lancet 1094 (2010)) at 1098.

Certain autoantibodies are biomarkers for RA, including the rheumatoid factor antibody ("RF antibody"), and the anticyclic-citrullinated peptide antibody ("anti-CCP").[2] Exhibit 33.3 (Scott) at 1095-96. RF antibody is found in approximately 80 percent of people with rheumatoid arthritis. Dorland's Illustrated Medical Dictionary 676 (32d ed. 2012). RA is sometimes categorized by whether or not it is anti-CCP positive, that is anti-CCPs are present, or anti-CCP negative, anti-CCPs are not present. See Kathleen D. Pagana & Timothy J. Pagana, Mosby's Manual of Diagnostic and Laboratory Tests 72 (5th ed. 2014).

There is evidence of a preclinical stage of RA in which the patient may not yet exhibit physical symptoms but could test positive for biomarkers associated with RA. Exhibit D (Markus M.J. Nielen et al., Specific Autoantibodies Precede the Symptoms of Rheumatoid Arthritis, 50 Arthritis & Rheumatism 380 (2004)) at 380-81. Studies from blood banks demonstrate that antibodies may be detected years before a person displays symptoms of RA. Exhibit D (Nielen) at 381; exhibit E (F.A. van Gaalen et al., Autoantibodies to Cyclic Citrullinated Peptides Predict Progression to Rheumatoid Arthritis in Patients with Undifferentiated Arthritis, 50 Arthritis & Rheumatism 709 (2004)) at 709; exhibit 35.2 (V. Michael Holers et al., Antibodies to Citrullinated Proteins: Pathogenic and Diagnostic Significance, 9 Current Rheumatology Reports 396 (2007)) at 396; Tr. 57, 154-55.

Smoking seems to be a risk factor for anti-CCP positive RA. Exhibit 31.1 (Shah) at 2743; exhibit 33.3 (Scott) at 1096. In contrast, genetic risk factors are associated with either anti-CCP positive or anti-CCP negative RA. Exhibit 33.3 (Scott) at 1096. Long-term exposure to tobacco smoke might induce citrullination of cellular proteins in the lungs and enhance the expression of a neoepitope capable of inducing self-reactivity. Exhibit 31.1 (Shah) at 2743; exhibit 33.3 (Scott) at 1096; Tr. 51.

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[2] The various sources cited by the parties abbreviate this peptide-related antibody differently. For consistency, when referencing this antibody, this decision always uses anti-CCP, like Shah, exhibit 31.1. Anti-CCPs are formed by the conversion of amino acid ornithine to arginine, and the presence of anti-CCP antibodies indicates a high likelihood a patient has rheumatoid arthritis. Kathleen D. Pagana & Timothy J. Pagana, Mosby's Manual of Diagnostic and Laboratory Tests 72 (5th ed. 2014).

In addition to the results available from blood tests, the existence of carpal tunnel syndrome ("CTS") might be an early indicator of RA based on a correlation between the two. Exhibit 33.1 (Isam Atroshi et al., Prevalence of Carpal Tunnel Syndrome in a General Population, 282 Journal of the American Medical Association 153 (1999)) at 158. Dr. Lightfoot testified that he recognized carpal tunnel syndrome as an early manifestation of RA in several of his patients. Tr. 108-09, 131, 167-68. But, because CTS affects such a large portion of the population, there is no significant statistical correlation that can be drawn connecting CTS and RA. Exhibit 33.2 (Kwang-Huyn Lee et al., The Incidence of Carpal Tunnel Syndrome in Patients with Rheumatoid Arthritis, International Journal of Rheumatic Diseases, Sep. 2014) at 1; Tr. 96-97 (Dr. Charlesworth).

Vaccinations have also been proposed as an environmental trigger in the onset or worsening of RA in that they might serve as the basis for a viral exposure which may activate an inflammatory reaction that develops into RA. Exhibit 31.9 (J. Sibilia & J.F. Maillefert, Vaccination and Rheumatoid Arthritis, 61 Annals of the Rheumatic Diseases 575 (2002)) at 575.

Facts

Ms. Bean-Sasser was born in 1958. Her family's medical history includes an uncle who suffered from rheumatoid arthritis. Exhibit 3 at 69.

Distant Medical History

Most of her remote medical history appears not to be relevant, with two exceptions. The first potentially-relevant item in Ms. Bean Sasser's remote medical history is her smoking. In January and February 2011, Ms. Bean-Sasser reported a ten- year history of smoking one pack per day (PPD). Exhibit 13 at 259; exhibit 14 at 262. In November 2011, Ms. Bean-Sasser reported a half PPD habit for 16 years, and an 18 year period of having quit. At the time she made this statement, Ms. Bean-Sasser was 52 years old, placing her onset of smoking at 18 years old. Exhibit 17 at 294. In May 2012, Ms. Bean-Sasser reported smoking one PPD since the age of 21, quitting in 1993. Exhibit 17 at 275. Born in 1958, Ms. Bean-Sasser turned 21 years old in 1979. Under these assumptions Ms. Bean-Sasser's smoking history would be slightly longer than the previously mentioned 10 years, perhaps 13-14 years. Id. In contrast, in August 2013, Ms. Bean-Sasser reported she quit smoking in 1989, as opposed to 1993. Exhibit 18 at 326. Other exhibits throughout the record are roughly consistent with the above, and establish

the same general order of magnitude for Ms. Bean-Sasser's smoking habit. E.g., exhibit 21 at 997; exhibit 22 at 1298; exhibit 23 at 1891; exhibit 24 at 2355. After she first quit smoking, Ms. Bean-Sasser smoked a half PPD from March 2011 through March 2012. Tr. 19-20.

The second potentially relevant item in Ms. Bean-Sasser's medical history is that in 2004, she was diagnosed as suffering from carpal tunnel syndrome. Exhibit 3 at 68. She developed carpal tunnel syndrome while working as a nurse, a career which began in approximately 1977. Exhibit 27 at 2804-05 (affidavit of Ms. Bean-Sasser); exhibit 23.1 (Ms. Bean-Sasser's deposition) at 2027.

Vaccination and Diagnosis of Rheumatoid Arthritis

In April 2010, Ms. Bean-Sasser was still working as a nurse. While tending to a patient, Ms. Bean-Sasser was exposed to that person's blood. According to the petition, Ms. Bean-Sasser's supervisor informed her that guidelines issued by the Center for Disease Control required that she receive a booster dose of the hepatitis B vaccine. Pet. at 2-6; accord exhibit 23.1 (Ms. Bean-Sasser's deposition) at 2043. Ms. Bean-Sasser received this dose on May 11, 2010.[3] Exhibit 6 at 146.

Approximately 11 hours after vaccination, Ms. Bean-Sasser began to experience pain in her left wrist. Jt. Stip. of Onset, filed May 19, 2014, at 1. After the pain worsened, Ms. Bean-Sasser went to an emergency room on May 16, 2010. Exhibit 2 at 21-40. An emergency room doctor, Clayton Overton, recorded Ms. Bean-Sasser's chief complaint as suffering from pain and swelling in both of her wrists and ankles, and her right shoulder. Dr. Overton also noted "all joints no erythema, warmth or effusions." Exhibit 2 at 22. He ordered various tests and diagnosed Ms. Bean-Sasser as suffering from "arthralgias, diffuse." Id. He did not order any steroids and recommended that Ms. Bean-Sasser review the results of the testing with her primary care provider. Id.

One of the tests showed that Ms. Bean-Sasser was positive for the RF antibody. Exhibit 2 at 27.

[3] Ms. Bean-Sasser filed a workers' compensation claim, which settled. Pet'r's Status Rep., filed Sept. 16, 2014. See exhibits 19-23. In that litigation, Ms. Bean-Sasser provided information about her injury that she filed into this case.

Ms. Bean-Sasser saw her primary care provider, Paul Windham, M.D., on June 4, 2010. Dr. Windham reviewed the available records and test results from Ms. Bean-Sasser's visit to the emergency room. After reviewing Ms. Bean-Sasser's history in relation to her current complaints, Dr. Windham diagnosed her with polyarthritis. Exhibit 2 at 49.

Dr. Windham ordered additional testing, including a test for anti-CCP antibodies. The result of this test established that Ms. Bean-Sasser suffers from rheumatoid arthritis. See exhibit 28 (Dr. Charlesworth's report) at 2813; exhibit A (Dr. Lightfoot's report) at 4.

When this test was pending, Dr. Windham investigated the origins of his patient's rheumatoid arthritis. Dr. Windham wrote: "I believe it is serendipity that when she was given her vaccine on 05/11/2010 her arthritic symptoms began later the same day. It is medically more probable than not that her rheumatoid arthritis has not arisen from or been incurred in the course of her employment." Exhibit 2 at 51; see also id. at 55.

Treatment for Rheumatoid Arthritis

Following her diagnosis, Ms. Bean-Sasser saw a variety of doctors. After she sought benefits from the workers' compensation program, Ms. Bean-Sasser saw Robert Blau, M.D., an internist. Exhibit 3. Dr. Blau recorded that Ms. Bean-Sasser researched whether the hepatitis B vaccine is connected to rheumatoid arthritis. Ms. Bean-Sasser told Dr. Blau that "there have not been any large studies done. Although nothing has been proven, there are a lot of people who have experienced this." Exhibit 3 at 68. Dr. Blau's report shows his view was that it was unlikely that it was just coincidence Ms. Bean-Sasser started showing symptoms 11 hours after she received the vaccine. Noting the existence of medical literature from France and England linking the hepatitis B vaccine to arthritis and Ms. Bean-Sasser's genetic susceptibility, Dr. Blau concluded that the hepatitis B vaccine was related to Ms. Bean-Sasser's rheumatoid arthritis. Exhibit 3 at 79-80; see also id. at 108-09; Tr. 118-19.

On September 29, 2010, Ms. Bean-Sasser saw Paul Utz, M.D., a rheumatologist at Stanford University. Exhibit 4. Ms. Bean-Sasser brought the results of laboratory studies with her for Dr. Utz to review. Id. at 130. Dr. Utz recounted that Ms. Bean-Sasser came in "for evaluation and to determine whether or not the vaccine could have been causative or related in some way to her

symptoms." Id. at 131. Dr. Utz obtained a detailed history and performed a physical examination.

Based upon information available, Dr. Utz reached conclusions about Ms. Bean-Sasser. He stated that Ms. Bean-Sasser's positive antibodies existed prior to her vaccination. Exhibit 4 at 133. Dr. Utz, however, did not completely exonerate the hepatitis B vaccine as contributing to Ms. Bean-Sasser's rheumatoid arthritis. With respect to etiology, Dr. Utz stated that: "Her antibody test 5 days [after vaccination] would very strongly suggest that she had preexisting positive antibodies as they certainly could not form that quickly. It is certainly possible, however, that she had been in the presymptomatic phase of rheumatoid arthritis and then the hepatitis B vaccine acted as the environmental trigger to actually give her systemic disease." Id. Dr. Utz ordered additional blood tests and prescribed Plaquenil. Id.

A rheumatologist closer to Ms. Bean-Sasser's residence, William Reeder, saw her on January 21, 2011. Exhibit 18 at 377-79. In the history of present illness section, Dr. Reeder recorded that Ms. Bean-Sasser "has been experiencing several months of diffuse joint pain with swelling . . . . She has not been able to work. This seemed to worsen after work related hepatitis vaccine exposure." Id. at 377. Dr. Reeder also examined her. His assessment included rheumatoid arthritis. He commented: Ms. Bean-Sasser "has an interesting history to [her] origin of rheumatoid arthritis. It appears to be related to immune stimulation due to hepatitis vaccine. Rare cases reported in literature. Rheumatoid arthritis should be conceived as a 'final common immunologic activity' to a variety of environmental stimuli in individuals with certain genetic and immunologic makeup." Id. at 378. Dr. Reeder adjusted her medications, ordered imaging tests, and wanted to see her in follow up in four weeks. Id. at 378-79.

After January 2011, Ms. Bean-Sasser has continued to be treated by Dr. Reeder and other physicians. The details of the subsequent course of her rheumatoid arthritis appear not to be relevant as neither Dr. Charlesworth nor Dr. Lightfoot attribute any significance to them. See exhibit 28 (Dr. Charlesworth's report) at 2812 ("Ms. Bean-Sasser had a complicated and aggressive course for her rheumatoid arthritis"); exhibit A (Dr. Lightfoot's report) at 5-8 (summarizing medical records).

Standards for Adjudication

A petitioner is required to establish her case by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1367 (Fed. Cir. 2000) (discussing special master's application of the "reasonable degree of medical certainty" standard to testifying experts); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty).

The elements of Ms. Bean-Sasser's case are set forth in the often cited passage from the Federal Circuit's decision in Althen: "(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).

Analysis

The analysis below focuses first on prong two of Althen, a logical sequence of cause and effect between the vaccination and injury, and then moves on to prong one, the medical theory. Althen, 418 F.3d at 1278. Prong three is addressed in the context of analyzing prongs one and two, and therefore is not broken out separately.

Prong Two – Vaccination as Cause of the Injury

Ms. Bean-Sasser claims that the May 11, 2010 hepatitis B vaccination caused her to develop RA. Pet'r's Posth'g Br., filed Aug. 10, 2015, at 9. In other words, but for the vaccination, she would not have developed RA. To assess the persuasiveness of this claim, it is helpful to look at Ms. Bean-Sasser's health on May 10, 2010, the day before the vaccination.

On May 10, 2010, Ms. Bean-Sasser's health included many factors relevant to RA:

- She was a 52 year old woman. Her gender and age mean that she was part of a demographic group in which RA occurs more frequently than the general population.
- She had a second-degree relative, an uncle, who suffered from RA. This family history means that Ms. Bean-Sasser may have inherited genes increasing the likelihood that she would develop RA.
- She had a history of smoking for at least ten years.[4] Smoking has been described as a factor that significantly increases the risk of developing RA.
- She already had RF antibodies.[5]

Dr. Lightfoot's opinion was that before vaccination, Ms. Bean-Sasser was already suffering from RA. Tr. 129. His opinion is persuasive, in part, because he has treated patients with RA for decades, and has been recognized as a leading rheumatologist. Tr. 101-06, 140-46. In determining when a disease began, special masters may reasonably rely upon the testimony of a specialist who routinely treats people with that disorder. Locane v. Sec'y of Health & Human Servs., 99 Fed. Cl. 715, 726-27 (2011), aff'd, 685 F.3d 1375 (2012); see also Terran v. Sec'y of

[4] Although Ms. Bean-Sasser had quit smoking but occasionally smoked after quitting (Tr. 19-20), the experts did not discuss whether quitting smoking decreases the risk to develop RA.

[5] Whether Ms. Bean-Sasser also had anti-CCP antibodies on May 10, 2010, is not known because she was not tested for them until June 2010. Thus, because there is no affirmative evidence that Ms. Bean-Sasser did have anti-CCP antibodies, it is assumed that she did not have those antibodies.

Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (special masters may "determine whether the testimony has a reliable basis in the knowledge and experience of [the relevant] discipline") (brackets in original) (citations and internal quotation marks omitted).

Ms. Bean-Sasser has little evidence to challenge Dr. Lightfoot's opinion. To start, Dr. Charlesworth has much less experience treating RA than Dr. Lightfoot. Tr. 30. He last diagnosed a patient with RA in 1995. Tr. 94-95; see also Tr. 43-45. While Dr. Charlesworth seemed to have an impressive knowledge of immunology, his experience in rheumatology and RA is considerably less than Dr. Lightfoot's experience in those areas.

To respond to Dr. Lightfoot's opinion that she was already suffering from RA before her vaccination, Ms. Bean-Sasser argues that by May 10, 2010, no doctor had diagnosed her with RA. Tr. 32, 58. The lack of diagnosis is accurate — it is true that the first diagnosis of RA followed the vaccination. However, the date of diagnosis is not always the same as the date of onset. Several cases have recognized that a person may suffer from a disease for a period without the disease being diagnosed. Somosot v. Sec'y of Health & Human Servs., No. 13-710V, 2014 WL 1926491 (Fed. Cl. Spec. Mstr. Apr. 24, 2014) (cerebral palsy), mot. for rev. denied, 118 Fed. Cl. 687, 693-94 (2014); White v. Sec'y of Health & Human Servs., No. 04-337V, 2011 WL 6176064, at *11 (Fed. Cl. Spec. Mstr. Nov. 22, 2011) (autism); W.C. v. Sec'y of Health & Human Servs., No. 07-456V, 2011 WL 4537877, at *6-8 (Fed. Cl. Spec. Mstr. Feb. 22, 2011) (multiple sclerosis), motion for review denied in relevant part and granted in non-relevant part, 100 Fed. Cl. 440, 451 (2011), aff'd in relevant part, 704 F.3d 1352, 1358-59 (Fed. Cir. 2013); Locane v. Sec'y of Health & Human Servs., No. 99-589V, 2011 WL 3855486, at *6 (Fed. Cl. Spec. Mstr. Feb. 17, 2011) (Crohn's disease), motion for review denied, 99 Fed. Cl. 715, 726 (2011), aff'd, 685 F.3d 1375 (Fed. Cir. 2012); Porter v. Sec'y of Health & Human Servs., No. 99-639V, 2008 WL 4483740, at *16 (Fed. Cl. Spec. Mstr. Oct. 2, 2008) (autoimmune hepatitis), motion for review granted sub nom. Rotoli v. Sec'y of Health & Human Servs., 89 Fed. Cl. 71 (2009), decision reinstated, 663 F.3d 1242, 1254 (Fed. Cir. 2011); Cloer v. Sec'y of Health & Human Servs., No. 05-1002, 2008 WL 2275574, at *7-9 (Fed. Cl. Spec. Mstr. May 15, 2008) (multiple sclerosis), aff'd, 85 Fed. Cl. 141, 148-49 (2008), rev'd, 603 F.3d 1341 (2010), aff'd on rehearing en banc, 654 F.3d 1322, 1339-40 (Fed. Cir. 2011) (en banc), cert. denied, Cloer v. Sebelius, 132 S.Ct. 1908 (2012).

Admittedly, a positive RF antibody test, alone, does not guarantee that the person will develop RA. Some people with a positive RF antibody test suffer from diseases other than RA. Other people with a positive RF antibody are actually free of recognized diseases. Tr. 77, 152. However, the burden of proof does not require fact-finding at a beyond a reasonable doubt level. A preponderance of evidence suffices. 42 U.S.C. § 300aa−13(a)(1).

Here, based on Dr. Lightfoot's expert opinion, it is more likely than not that Ms. Bean-Sasser suffered from RA before she was vaccinated. This finding means that she cannot prevail on a theory that the vaccine caused her RA. Locane, 685 F.3d at 1381 ("Given the Special Master's finding that the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").[6]

In determining it is more likely than not Ms. Bean-Sasser's RA existed before the hepatitis B vaccination, the undersigned has considered not only the reports of the experts, but also the reports of the treating doctors. Multiple treating doctors expressed opinions about the role played by the hepatitis B vaccine in Ms. Bean-Sasser's RA, and these various opinions conflict. The parties, unsurprisingly, emphasize the opinions (or portions of opinions) that support their position.

The Secretary points to the opinion of Dr. Windham. Resp't's Posth'g Br., filed Oct. 9, 2015, at 2-3. Before there was any litigation, Dr. Windham stated that Ms. Bean-Sasser's hepatitis B vaccination and RA were related to each other by "serendipity." Exhibit 2 at 51.

In contrast, Ms. Bean-Sasser cites a portion of Dr. Utz's report. Pet'r's Posth'g Br., filed Aug. 10, 2015, at 8-9. In Dr. Charlesworth's testimony, he emphasizes the part of Dr. Utz's statement identifying the vaccine as the trigger, "the hepatitis B vaccine acted as the environmental trigger to actually give her systemic disease." Tr. 39. The undersigned does not find this argument persuasive for three reasons.

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[6] Conceptually, Ms. Bean-Sasser could have pursued a theory that the hepatitis B vaccine significantly aggravated her pre-existing RA. See 42 U.S.C. § 300aa−11(c)(1)(C)(ii). However, she disclaimed any reliance on this theory. Prehr'g Order, filed May 29, 2015, at 2.

First, Ms. Bean-Sasser omitted a very contextually important portion of Dr. Utz's statement. In the sentence prior, Dr. Utz stated that Ms. Bean-Sasser's positive RF antibody test very strongly suggested that she had preexisting positive antibodies, as the positive antibodies could not form that quickly. Exhibit 4 at 133. That admission by Dr. Utz is consistent with the Secretary's expert report, in which Dr. Lightfoot also stated that the vaccination did not cause Ms. Bean-Sasser's rheumatoid arthritis. Exhibit A at 12; Tr. 115-16.

Second, this aspect of Dr. Utz's letter is ambiguous because the sentence relied on by Ms. Bean-Sasser begins "It is certainly possible." In its entirety, the sentence reads: "It is certainly possible, however, that she had been in the presymptomatic phase of rheumatoid arthritis and then the hepatitis B vaccine acted as the environmental trigger to actually give her systemic disease." Exhibit 4 at 133. The term "presymptomatic phase of rheumatoid arthritis" means that the process of rheumatoid arthritis was already beginning in her.[7]

It is unclear whether "it is certainly possible" refers to Ms. Bean-Sasser being in the presymptomatic phase of rheumatoid arthritis, the hepatitis B vaccine acting as the environmental trigger to give Ms. Bean-Sasser systemic disease, or both. Dr. Utz is not expressing his opinion on a more-likely-than-not basis. A treating doctor's testimony that "causation was 'not impossible' fails to provide support for causation at all." Paterek v. Sec'y of Health & Human Servs., 527 F. App'x 875, 883 (Fed. Cir. 2013).

Third, Dr. Utz does not explain why any environmental trigger was needed. Through Dr. Lightfoot, the Secretary presented evidence that showed people who test positive for the RF antibody are likely to develop RA. When the person with the antibody also happens to have a first-degree relative with RA, then the person's likelihood of developing RA is approximately 37 times greater than a person in the general population. Exhibit D (Nielen) at 384. Although Ms. Bean-Sasser's

[7] After the parties submitted briefs in this case, another special master ruled that a petitioner in the preclinical stage of RA could claim that a vaccination caused the RA. However, H.J. is distinguishable because that petitioner did not have any "laboratory tests confirming that preclinical state." H.J. v. Sec'y of Health & Human Servs., No. 11-301V, 2015 WL 6848357, at *8 (Fed. Cl. Spec. Mstr. Nov. 6, 2015).

family connection (an uncle) is at the second degree (rather than the first degree), her risk of developing RA was still increased. Tr. 75-76, 154-56.

While special masters must consider opinions of treating doctors, any statements by treaters are not "binding on the special master." 42 U.S.C. § 300aa−13(b). Furthermore, because the treating doctors have reached opposite conclusions, special masters cannot follow both opinions. See Contreras v. Sec'y of Health & Human Servs., No. 05-626V, 2013 WL 6698382, at *32-33 (Fed. Cl. Spec. Mstr. Nov. 19, 2013), mot. for rev. granted on other grounds and decision vacated, 116 Fed. Cl. 472 (2014), decision after remand, 2014 WL 8098606 (Fed. Cl. Spec. Mstr. Oct. 24, 2014), mot. for rev. denied, 121 Fed. Cl. 230 (2015), appeal docketed, No. 2015-5097 (Fed. Cir. June 19, 2015). Consistent with these principles in considering the record as a whole, the undersigned has weighed the opinions from the treating doctors, but finds them less persuasive than Dr. Lightfoot's expert opinion that Ms. Bean-Sasser suffered from RA before she was vaccinated. See 42 U.S.C. § 300aa−13(a) (special masters are obligated to consider the record as a whole).

To conclude this discussion of prong two, the undersigned finds Dr. Lightfoot's considered expert opinion very persuasive, especially in light of Ms. Bean-Sasser's other health factors relevant to RA. While some evidence from treating doctors suggests Ms. Bean-Sasser's May 11, 2010 vaccination was a factor in her subsequent RA, that evidence falls short of being persuasive. See Doe 11 v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (indicating that presence of evidence inconsistent with the special master's finding does not mean the special master's finding was not supported by substantial evidence).

Prong One – Medical Theory

Although the finding that Ms. Bean-Sasser is likely to have been suffering from RA before vaccination is enough to resolve her claim that the vaccination caused her RA, the theory that Ms. Bean-Sasser presented will also be evaluated. See 42 U.S.C. § 300aa−13(a) (special masters are obligated to consider the record as a whole). An analysis of Ms. Bean-Sasser's evidence for how the hepatitis B vaccine can cause RA, Althen prong one, requires resolution of two preliminary legal questions. After those are addressed, the merits of her theory are considered.

Capizzano and Althen Prong One

Ms. Bean-Sasser appears to assume that the outcome of Capizzano means that she has established the first Althen prong. She cited Capizzano in her memoranda, quoting the statement "[t]he fact that there is a possibility that the rheumatoid arthritis that appeared immediately after . . . vaccination was not caused by the vaccination does not prevent a finding that it is more likely than not that the vaccine caused the RA." Pet'r's Preh'g Br., filed April 27, 2015, at 6, 11, 20; Pet'r's Posth'g Br., filed Aug. 10, 2015, at 4, 7-8 (quoting Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006)). She also inquired about Capizzano during the hearing. Tr. 30 (Dr. Charlesworth), 134-36 (Dr. Lightfoot).

Ms. Bean-Sasser misunderstands the precedential value of the Federal Circuit's decision in Capizzano. "'A special master's acceptance of a theory in one case does not require him or her to accept the theory in subsequent cases involving similar facts or the same vaccine. Rather a different evidentiary record can lead to different outcomes.'" Bast v. Sec'y of Health & Human Servs., 117 Fed. Cl. 104, 124 (2014) (quoting Rickett v. Sec'y of Health & Human Servs., 468 F. App'x 952, 959 (Fed. Cir. 2011) (unpublished)). As medicine and science advance, knowledge about the causes of diseases and adverse effects of vaccinations is likely to increase. When the evidence differs, a different result is entirely plausible. Lehner v. Sec'y of Health & Human Servs., No. 08-554V, 2015 WL 5443461, at *40 (Fed. Cl. Spec. Mstr. July 22, 2015).

In Capizzano, the special master had preliminarily found that the evidence supported a finding that the hepatitis B vaccine can cause RA. The special master primarily relied upon a 1999 Maillefert study that reported four cases of rechallenge. Capizzano v. Sec'y of Health & Human Servs., No. 00-759V, 2004 WL 1399178, at *2 (Fed. Cl. Spec. Mstr. June 8, 2004) (citing Capizzano et al. v. Sec'y of Health & Human Servs., No. 00-759V, etc., 2003 WL 21432586 (Fed. Cl. Spec. Mstr. June 20, 2003)), mot. for rev. denied, 63 Fed. Cl. 227 (2004), vacated and remanded, 440 F.3d 1317 (Fed. Cir. 2006). After further examination, the special master stated that the petitioner "established that the hepatitis B vaccine can cause RA; however, she has failed to demonstrate that it did cause the injury." Id., 2004 WL 1399178, at *13.

On appeal, the Federal Circuit recited this procedural history. Capizzano, 440 F.3d at 1322. The parties did not dispute that Ms. Capizzano had satisfied the

first prong of Althen. Thus, the issue was whether she satisfied the second prong. Id. at 1325. The Federal Circuit held that with respect to the second Althen prong, the special master had imposed an evidentiary burden that was too high. Therefore, the Federal Circuit, which does not weigh evidence, vacated the underlying judgment and remanded the case. Id. at 1328.

This context demonstrates that Ms. Bean-Sasser's reliance on Capizzano is mistaken. There, the special master evaluated the evidence in that case and then reached a conclusion that the hepatitis B vaccine can cause RA in the context of a "rechallange." This precise issue was not before the Federal Circuit. Thus, the Federal Circuit's recitation of fact-finding by the special master does not transform those facts into a statement of law that binds special masters in subsequent cases.

As finders of facts, special masters must enjoy the liberty to reach different factual conclusions based upon the evidence presented. Althen, 418 F.3d at 1281 (a "special master's role is to assist the courts by judging the merits of individual claims on a case-by-case basis"); Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357, 1366 (Fed. Cir. 2000) ("a special master's task is to make a factual determination of causation based on the evidence in a particular case").

Here, the evidence in Ms. Bean-Sasser's case differs from the evidence discussed in Capizzano. Ms. Bean-Sasser did not introduce the Maillefert study that was the critical article in Capizzano. In addition, Ms. Bean-Sasser's case includes, as discussed below, an epidemiological study that was published years after Capizzano was decided. This variance in evidence means that Ms. Bean-Sasser cannot rely on the Federal Circuit's decision in Capizzano, and is required to meet her burden with evidence of her own.

Burden of Proof - Plausible versus Persuasive

The second legal issue concerns Ms. Bean-Sasser's burden of proof. She argues that she satisfies the first Althen prong by presenting a "plausible" theory. See Pet'r's Preh'g Br., filed Apr. 27, 2016, at 9, 18 (citing Dr. Charlesworth's report); Pet'r's Posth'g Br., filed Aug. 10, 2015, at 3 (quoting Dr. Charlesworth's testimony), 12 (quoting Dr. Lightfoot's testimony); but see id. at 7 (asserting that Dr. Charlesworth's opinion is "plausible, and more likely than not"). Similarly, she also argued that she fulfilled prong one of Althen simply by presenting a theory. Id. at 4.

The Secretary disagreed. In the Secretary's view, "'simply identifying a 'plausible' theory of causation is insufficient for petitioner to meet her burden of proof.'" Resp't's Preh'g Br., filed May 11, 2015, at 6, quoting La Londe v. Sec'y of Health & Human Servs., 746 F.3d 1334, 1339 (Fed. Cir. 2014).

The Federal Circuit's statement in La Londe controls. Ms. Bean-Sasser must present a persuasive theory to explain how the hepatitis B vaccine can cause RA.

Merits of the Presented Theory

Ultimately, at the hearing, Ms. Bean-Sasser did not present a theory that was persuasive. The presentation was relatively cursory, taking up fewer than ten transcript pages on direct examination. See Tr. 34-37, 41-42.

The testimony about how the hepatitis B vaccine can cause RA may have been relatively short because during the hearing, Ms. Bean-Sasser and Dr. Charlesworth asserted a new theory – a theory not presented in her expert reports or prehearing brief. In Dr. Charlesworth's report, he disclosed a theory that the hepatitis B vaccine can cause immune complexes, also known as a Gel and Combs type III reaction. Exhibit 30 at 2833. Likewise, in her brief before the hearing, Ms. Bean-Sasser also advanced this type of reaction. Pet'r's Preh'g Br. at 6-7.

However, at hearing, Dr. Charlesworth proposed a different theory. He opined that the hepatitis B vaccine can stimulate a part of the innate immune system, toll-like receptors, to produce pro-inflammatory cytokines that lead to RA. Tr. 36.[8] During his direct testimony, Dr. Charlesworth did not discuss any filed

[8] If Ms. Bean-Sasser had continued to advance a Gel-Combs type III reaction, she would have had difficulty meeting the appropriate temporal relationship prong of Althen. See Tr. 88-94. Dr. Charlesworth stated that a type III reaction may occur during a 7-10 day window. Exhibit 30 at 2833. For re-exposure to an antigen, the window could be potentially as short as two days. Exhibit 35.7 (Carol A. Langford & Anthony S. Fauci, The Vasculitis Syndromes, in Harrison's Principles of Internal Medicine (Dan L. Longo et al. eds.,18th ed. 2012)) at 2800 (note, exhibit 35.7 is misidentified on the first page of exhibit 35 as authored by Ankoor Shah & E. William St. Clair). However, Ms. Bean-Sasser's reaction took place in 11 hours. Jt. Stip. of Onset, filed May 19, 2014, at 1. An onset that is too early precludes compensation. Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008).

articles related to the theory that the hepatitis B vaccine interacts with toll like receptors (frequently abbreviated "TLRs") to cause RA.[9] Similarly, Ms. Bean-Sasser does not cite any articles to show the reliability of this theory in her memorandum. See Pet'r's Posth'g Br., filed Aug. 10, 2015; Vaccine Rule 8(f)(1).

As the party with the burden of presenting preponderant evidence, Ms. Bean-Sasser should show that the opinion of her expert is reliable and persuasive. Moberly, 592 F.3d at 1322 ("A petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'") (quoting Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)); Althen, F.3d at 1278 ("[petitioner's] burden is to show by preponderant evidence that the vaccination brought about her injury"). In the Vaccine Program, special masters are authorized to evaluate causation opinions according to the standards set forth in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). Terran, 195 F.3d at 1316; Davis v. Sec'y of Health & Human Servs., 94 Fed. Cl. 53, 66 (2010), aff'd without opinion, 420 F. App'x 973 (Fed. Cir. 2011). Yet, Ms. Bean-Sasser has not produced any evidence that demonstrates the reliability of Dr. Charlesworth's theory that the hepatitis B vaccine stimulates TLRs and this stimulation leads to RA. For example, Ms. Bean-Sasser did not submit any evidence that the theory was tested, the theory was consistent with articles from peer-reviewed journals, or that the theory was generally accepted among immunologists or rheumatologists. This lack of support greatly diminishes the persuasive value of Dr. Charlesworth's opinion. See Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 134 (2011) ("it should be obvious to petitioner that a scientific theory that lacks any empirical support will have limited persuasive force"), aff'd without opinion, 463 F. App'x 932 (Fed. Cir. 2012). Judges at the Court of Federal Claims have explained that special masters do not err when they require petitioners establish the reliability of an expert's opinion. See La Londe v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 201 (2013)

[9] In his testimony, Dr. Charlesworth mentioned an article about how people receiving dialysis may not respond to the hepatitis B vaccine. Tr. 36, 53. A close examination of the record reveals at least some support for this statement. See exhibit 35.10 (Alan R. Shaw & Mark B. Feinberg, Vaccines, in Clinical Immunology Principles and Practice (Robert R. Rich ed., 4th ed. (2013)) at 1115. However, the underlying study is not part of the record.

(the petitioner's expert "could not back up his hypothesis with a reliable medical or scientific explanation. The special master . . . quite properly required petitioner to carry her burden to bring forward a reliable medical or scientific explanation"), aff'd, 746 F.3d 1334, 1340 (Fed. Cir. 2014); Langland v. Sec'y of Health & Human Servs., 109 Fed. Cl. 421, 441 (2013) ("the Special Master did not commit a legal error by requiring a sufficiently-detailed explanation of how" a vaccine can cause a disease); Taylor v. Sec'y of Health & Human Servs., 108 Fed. Cl. 807, 819 (2013) ("the mere existence" of expert testimony about a theory "is insufficient to satisfy the burden of showing a 'persuasive' medical theory—this theory must also preponderate").

In addition to this deficit in Ms. Bean-Sasser's case-in-chief, contrary evidence further undermined the persuasiveness of her claim. See Bazan, 539 F.3d at 1353-54 (special master may consider evidence adverse to the petitioner's claim in determining whether the petitioner established her case). An article reported that an epidemiological study involving more than 1 million people who received more than 200,000 doses of the hepatitis B vaccine failed to detect a "statistically significant association between exposure to hepatitis B vaccine and RA." Exhibit 35.11 (Paula Ray et al., Risk of Rheumatoid Arthritis Following Vaccination with Tetanus, Influenza and Hepatitis B Vaccines Among Persons 15-59 Years of Age, 29 Vaccines 6592 (2011)) at 6594-96. The authors noted that due to limits in sample size, "if a very small risk of RA in association with vaccines does exist, a larger study would be needed to detect it." Id. at 6596.

This was the view of Dr. Charlesworth. He opined that statistics cannot detect rare events and, in his view, Ms. Bean-Sasser's case constituted a rare adverse reaction to the hepatitis B vaccine. Tr. 41, 48-49.

As explained above, this case's evidence does not persuasively show that the hepatitis B vaccine can cause RA through activation of TLRs. If there is any risk from hepatitis B vaccination, the risk is much less than other factors present in Ms. Bean-Sasser, such as genetics and smoking. Ms. Bean-Sasser has not demonstrated that but for the vaccination, she would not have developed RA. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999).

In short, even if Ms. Bean-Sasser had shown that she was not suffering from RA before her vaccination, the lack of a persuasive theory causally connecting the hepatitis B vaccine to RA is an independent reason for denying her compensation.

Conclusion

After receiving the hepatitis B vaccine in 2010, Ms. Bean-Sasser was diagnosed with rheumatoid arthritis. She claims that the hepatitis B vaccine caused her rheumatoid arthritis. However, this assertion necessarily assumes that she was not suffering from that disease before vaccination. In fact, a more detailed review of the evidence reveals that a preponderance of the evidence supports a finding that Ms. Bean-Sasser either was already suffering from an undiagnosed case of rheumatoid arthritis, or had so many risk factors for the disease that she was likely to develop rheumatoid arthritis in any event.

Consequently, Ms. Bean-Sasser has not established that she is entitled to compensation. The Clerk's Office is instructed to enter judgment in accord with this decision.

IT IS SO ORDERED.

S/Christian J. Moran
Christian J. Moran
Special Master