

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS**

ELIZABETH SHAPIRO,	*	No. 99-552V
	*	Special Master Christian J. Moran
Petitioner,	*	
	*	
v.	*	Filed: April 27, 2011
	*	
SECRETARY OF HEALTH	*	Entitlement; hepatitis B
AND HUMAN SERVICES,	*	vaccine; thyroid condition;
	*	autoimmune disease; systemic
Respondent.	*	lupus erythematosus (SLE)

Clifford J. Shoemaker, Shoemaker and Associates, Vienna, VA., for petitioner;
Lynn E. Ricciardella, United States Dep't of Justice, Washington, D.C., for
respondent.

PUBLISHED DECISION DENYING COMPENSATION¹

Elizabeth Shapiro filed a petition seeking compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-1 *et seq.* (2006). Ms. Shapiro alleged that a series of hepatitis B vaccinations caused her to develop thyroid disease and, subsequently, systemic lupus erythematosus (“SLE”).

¹ Because this published decision contains a reasoned explanation for the special master’s action in this case, the special master intends to post it on the United States Court of Federal Claims’s website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

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

The first theory Ms. Shapiro alleges is that the hepatitis B vaccinations caused her to suffer a thyroid dysfunction.² The weight of the evidence shows that Ms. Shapiro actually suffered from a thyroid dysfunction before the vaccinations. Thus, the vaccinations could not have caused Ms. Shapiro's thyroid disease and she is not entitled to compensation for this condition.

Ms. Shapiro's second claim is that the hepatitis B vaccinations caused her to suffer SLE.³ Ms. Shapiro claims that her SLE was triggered within two to three

² The thyroid is a gland that controls one's metabolic rate. Tr. 175. The thyroid can be overactive or underactive. When overactive, the condition is called hyperthyroidism. Dorland's Illustrated Medical Dictionary (30th ed. 2002) at 889. When the gland is underactive, hypothyroidism results. Dorland's at 900.

Hypothyroidism occurs when there is a "deficiency of thyroid activity." Manifestations of this condition include a decrease in one's basal metabolic rate, fatigue, and lethargy. It is seen more often in women than men. Dorland's at 900. "The commonest cause of hypothyroidism in developed countries is autoimmune thyroiditis. . . . Autoimmune thyroiditis generally causes a slow failure of thyroid hormone production, thus symptoms may be insidious, developing over years." Exhibit E, tab 18 (Bijay Vaidya & Simon HS Pearce, "Management of hypothyroidism in adults," 337 British Medical Journal 284 (2008)) at 284.

The alternative type of thyroid disease is hyperthyroidism, which occurs when there is "excessive production of . . . thyroid hormones." Hyperthyroidism is marked by such symptoms as palpitations, fatigability, nervousness and tremor, and weight loss. Dorland's at 889. A specific type of hyperthyroidism is known as a "thyroid storm," which can be a life-threatening event. Exhibit E, tab 19 (David S Cooper, "Hyperthyroidism," 362 Lancet 459 (2003)) at 460; see also tr. 290-92.

³ SLE "is a chronic multisystem autoimmune disease of unknown aetiology." SLE is characterized by flare and remissions and can involve any organ or body system. The organs most frequently affected by SLE are the kidneys and the brain. Exhibit 91 at 4 (Maria L. Bertolaccini et al., "Systemic Lupus Erythematosus," Diagnostic Criteria in Autoimmune Diseases (Yehuda Shoenfeld et al. eds., 2008)).

Early indicators of SLE are fatigue, fever, or anorexia. Id. Other manifestations include, but are not limited to, arthritis, renal disorder, neurologic disorder, antinuclear antibody, and the malar rash. The malar rash, or butterfly rash as it is commonly known, occurs in up to 85% of SLE patients making it the most characteristic feature of this disease. Id. at 5.

The anti-nuclear antibody (ANA) test is frequently used to test for SLE. ANA is present "in more than 95% of individuals with lupus." Id. at 4. However,

weeks after she received the second and third dose of the hepatitis B vaccine. The evidence does not preponderate in favor of finding this temporal sequence. Accordingly, Ms. Shapiro is not entitled to compensation for her SLE. The reasons for this decision follow.

I. Procedural History

Ms. Shapiro filed a petition for compensation on August 2, 1999, which was near the last day petitions alleging that a hepatitis B vaccine caused an injury before August 6, 1997, could be filed. See 42 U.S.C. § 300aa-16(b); 63 Fed. Reg. 25777, 25778 (clarifying the date on which the hepatitis B vaccine was added to the vaccine injury compensation table). No medical records were filed with the petition, although the statute requires those records to be filed. See 42 U.S.C. §300aa-11(c). In April 2000, a special master stayed the case. Although not reflected on the docket, the stay reflected efforts to develop a method to resolve the numerous cases in which petitioners alleged that the hepatitis B vaccine caused them an injury. Ultimately, these attempts did not succeed for this case.

In March 2002, the first sets of medical records were filed by Ms. Shapiro (exhibits 1-7). Additional records (exhibits 8-18) were filed between May through August 2002, but then several years passed with inactivity. Activity resumed in 2006, when the case was reassigned to another special master. On May 26, 2006, respondent filed her report pursuant to Vaccine Rule 4, asserting that Ms. Shapiro had failed to establish that she was entitled to compensation.

Following respondent's report, Ms. Shapiro submitted case reports (exhibits 19-20), as well as affidavits (exhibits 21-27). Ms. Shapiro then filed her affidavit on June 29, 2006, in which she set forth her recollection of what happened to her when she received her three hepatitis B vaccinations on April 13, 1992, September 21, 1992, and February 8, 1993. Exhibit 39 (affidavit, dated June 27, 2006). As discussed below, Ms. Shapiro asserted that she experienced health problems that are not reflected in any medical records created in 1992 through 1993.

Ms. Shapiro's assertions about her health in 1992 and 1993 are the basis of an opinion given by Dr. Joseph Bellanti in June 2006. Ms. Shapiro's assertions allow Dr. Bellanti to state that her symptoms worsened after each dose of the

these ANA antibodies can be present in healthy individuals and may indicate other diseases. Id. at 7.

hepatitis B vaccine, a pattern known as “challenge-rechallenge.” For Ms. Shapiro, her sequence of adverse reactions resulted in the development of SLE. Although Dr. Bellanti mentions that Ms. Shapiro has suffered from hypothyroidism, Dr. Bellanti does not state that the hepatitis B vaccine caused a thyroid problem. Exhibit 28.

Respondent filed the report of Dr. Alan Brenner and his curriculum vitae on December 20, 2006. Exhibits A and B. Dr. Brenner’s report concludes that there is no association between Ms. Shapiro’s medical conditions and her receipt of the hepatitis B vaccine. He states that while her history suggests the possibility of an underlying immunopathy, possibly even SLE, the medical records do not establish an association between the vaccine and onset of the condition. Further, Dr. Brenner opines that many of Ms. Shapiro’s subsequent medical problems were shown to be the result of gastrointestinal and gynecologic abnormalities. Exhibit A at 12.

Ms. Shapiro filed a report from a second expert, Dr. Yehuda Shoenfeld, on January 8, 2007. Exhibit 53. Dr. Shoenfeld serves as the head of the Department of Medicine “B” Sheba Medical Center, and the head of the Center for Autoimmune Diseases at Sheba Medical Center, Tel-Aviv University, Israel. He has written more than 1,500 articles in peer-reviewed journals and more than 20 books, one of which includes the “first trial in the world to compile the diagnostic criteria for more than 100 different autoimmune diseases.” Dr. Shoenfeld also served as editor and founder of the journal, Autoimmunity Reviews. Tr. 162; exhibit 53 at 18-109 (curriculum vitae).

Dr. Shoenfeld asserts that Ms. Shapiro likely had a genetic predisposition to autoimmune disease, and if she had not received the hepatitis B vaccine, she would not have developed an autoimmune condition. Dr. Shoenfeld opines that without exposure to the vaccine, Ms. Shapiro could have been asymptomatic for her life. He primarily relies on the theories of molecular mimicry and polyclonal activation to support his conclusions that the hepatitis B vaccine can trigger an autoimmune reaction. Exhibit 53 at 9-11. In Dr. Shoenfeld’s conclusion, he links the three hepatitis B vaccinations to Ms. Shapiro’s thyroid disease and to her SLE. Id. at 14.

In 2007, the case was reassigned to the undersigned and a status conference was held. During this conference, respondent indicated that she wanted to file a supplemental expert report from Dr. Brenner to respond to Dr. Shoenfeld. However, on October 22, 2007, respondent’s status report stated that she no longer could file this report due to Dr. Brenner’s health.

Instead, respondent filed a responsive expert report from Dr. Brian Ward. Exhibit C. Dr. Ward holds board certifications in internal medicine, infectious diseases, and microbiology. He has published in the field of infectious diseases and vaccines, and he reviews articles for more than 20 journals. Dr. Ward has additionally held the position of associate editor for the journal of Human Vaccines. Tr. 241-45; exhibit D (curriculum vitae).

Dr. Ward's report states that Ms. Shapiro was becoming hypothyroid long before she received her first dose of the vaccine. Exhibit C at 10-11. Responding to Dr. Bellanti's and Dr. Shoenfeld's arguments about the hepatitis B vaccine triggering an autoimmune disease, Dr. Ward states that both large and small studies indicate that "inactivated vaccines," such as the hepatitis B vaccine, can generally be administered to those with autoimmune conditions (including SLE) "without causing these diseases to 'flare'." Id. at 6, citing exhibit E-12 (Katia Akemi M. Kuruma et al., "Safety and efficacy of hepatitis B vaccine in systemic lupus erythematosus," 16 Lupus 350 (2007)); exhibit E-6 (SG O'Neill & DA Isenberg, "Immunizing patients with systemic lupus erythematosus: a review of effectiveness and safety," 15 Lupus 778 (2006)).

After the parties filed these reports and supporting medical literature, a hearing was scheduled for August 11-12, 2008, in Washington, D.C. A medical issue prevented Ms. Shapiro from participating on that date and the hearing was held on November 24, 2008. Ms. Shapiro and Dr. Shoenfeld testified in person. A second entitlement hearing was held on January 8, 2009, in Washington, D.C. to allow respondent to present her case. Dr. Ward testified in person.

After the hearings, Ms. Shapiro filed additional medical articles cited by Dr. Shoenfeld for the first time during the hearing as well as additional articles on thyroid disease. A status conference was then held, during which respondent stated that because of Dr. Brenner's death, he could not be called to testify. The parties agreed that both Dr. Brenner's and Dr. Bellanti's reports constituted evidence and should be evaluated for their persuasiveness. However, the parties did not place great importance on opinions of either Dr. Bellanti or Dr. Brenner in their post-hearing briefs.⁴ Instead, the parties' briefs emphasized the opinions of Dr. Shoenfeld and Dr. Ward, who provided written opinions and testified.

⁴ Although Ms. Shapiro omits any discussion of Dr. Bellanti in her initial brief, her reply discusses the challenge-rechallenge paradigm mentioned in Dr. Bellanti's report. Pet'r Reply at 6. Dr. Bellanti's analysis rests upon a mistaken understanding of the facts. Specifically, Dr. Bellanti asserts that Ms. Shapiro's health was fine before she received the first dose of the hepatitis B vaccine, Exhibit

A scheduling order, dated February 19, 2009, directed the parties to file status reports indicating whether additional evidence was needed, considering seven points outlined by the special master. This order encouraged the parties to consider laboratory reports showing both normal and abnormal results for Ms. Shapiro's thyroid. On August 4, 2009, petitioner filed a supplemental report from Dr. Shoenfeld, which attempted to address the seven points. In this report, Dr. Shoenfeld reaffirms his earlier conclusion, stating that Ms. Shapiro not only has SLE, satisfying four out of the 11 lupus criteria, but also that her condition is vaccine-related, fulfilling the three Althen prongs. Exhibit 114 at 10-11.

In response, respondent submitted a supplemental expert report from Dr. Ward. Responding to Dr. Shoenfeld's claims of causation, Dr. Ward states that Dr. Shoenfeld presented "general theories of causation," while failing to provide "substantive evidence" to support these theories. He explains that Dr. Shoenfeld has failed to establish a temporal association between the vaccinations Ms. Shapiro received and her subsequent medical events, stating that the sequence of events suggested by Dr. Shoenfeld "is not supported by the medical records or by current science." Exhibit I at 10-11.

In a status conference held on November 19, 2009, Ms. Shapiro was ordered to file any additional medical literature and/or any affidavits by December 30, 2009. Ms. Shapiro filed a motion for enlargement of time to file this information, which prompted another status conference held on January 21, 2010. During this conference, the parties agreed that after petitioner filed the outstanding medical literature and a supplemental affidavit of Ms. Shapiro, the evidentiary record would be closed. Ms. Shapiro filed the additional medical literature and affidavit on January 27-28, 2010. The parties then submitted post-hearing briefs and this case is ready for adjudication.

II. Facts

The first matter that must be decided concerns Ms. Shapiro's medical history during the years 1991 through 1994. Ms. Shapiro's health during these four years is critical to evaluating her claim because this period presents her health just

28 at 1-2. Ms. Shapiro has not established this assertion. See section IV.B.1. When an expert bases his opinion on facts not substantiated, a special master may reject that expert's opinion. Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

before, during, and just after she received the hepatitis B vaccine. The factual disputes arise because Ms. Shapiro has asserted that before she received the hepatitis B vaccine, she was healthy. Other evidence calls this assertion into question.

A. Standard for Finding Facts

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

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

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

Appellate authorities have accepted the reasoning supporting a presumption that medical records created contemporaneously with the events being described are accurate and complete. A notable example is Cucuras in which petitioners asserted that their daughter, Nicole, began to have seizures within one day of receiving a vaccination, although medical records created around that time suggested that the seizures began at least one week after the vaccination. Cucuras, 993 F.3d at 1527. A judge reviewing the special master’s decision stated that “In light of [the parents’] concern for Nicole’s treatment . . . it strains reason to conclude that petitioners would fail to accurately report the onset of their daughter’s symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of

seizures a week after they in fact occurred.” Cucuras v. Sec’y of Health & Human Servs., 26 Cl. Ct. 537, 543 (1992), aff’d, 993 F.2d 1525 (Fed. Cir. 1993).

Decisions by judges of the Court of Federal Claims have followed Cucuras in affirming findings by special masters that the lack of contemporaneously created medical records can contradict a testimonial assertion that symptoms appeared on a certain date. E.g. Doe v. Sec’y of Health & Human Servs., 95 Fed. Cl. 598 (2010); Doe/17 v. Sec’y of Health & Human Servs., 84 Fed. Cl. 691, 711 (2008); Ryman v. Sec’y of Health & Human Servs., 65 Fed. Cl. 35, 41-42 (2005); Snyder v. Sec’y of Health & Human Servs., 36 Fed. Cl. 461, 465 (1996) (stating “The special master apparently reasoned that, if Frank suffered such [developmental] losses immediately following the vaccination, it was more likely than not that this traumatic event, or his parents’ mention of it, would have been noted by at least one of the medical record professionals who evaluated Frank during his life to date. Finding Frank’s medical history silent on his loss of developmental milestones, the special master questioned petitioner’s memory of the events, not her sincerity.”), aff’d, 117 F.3d 545, 547-48 (Fed. Cir. 1997).

The presumption that contemporaneously created medical records are accurate and complete, however, is rebuttable. For cases alleging a condition found in the Vaccine Injury Table, special masters may find when a first symptom appeared, despite the lack of a notation in a contemporaneous medical record. 42 U.S.C. § 300aa-13(b)(2). By extension, special masters may engage in similar fact-finding for cases alleging an off-Table injury. In such cases, special masters are expected to consider whether medical records are accurate and complete.

In weighing divergent pieces of evidence, contemporaneously written medical records are usually more significant than oral testimony. Cucuras, 993 F.2d at 1528. However, compelling oral testimony may be more persuasive than written records. Campbell ex rel. Campbell v. Sec’y of Health & Human Servs., 69 Fed. Cl. 775, 779 (2006) (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); Camery v. Sec’y of Health & Human Servs., 42 Fed. Cl. 381, 391 (1998) (this rule “should not be applied inflexibly, because medical records may be incomplete or inaccurate”); Murphy v. Sec’y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff’d, 968 F.2d 1226 (Fed. Cir. 1992).

The relative strength or weakness of the testimony of a fact witness affects whether this testimony is more probative than medical records. An assessment of a fact witness’s credibility usually involves consideration of the person’s demeanor while testifying. Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1379

(Fed. Cir. 2009); Bradley v. Sec’y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The facts of Ms. Shapiro’s case will be found in accord with the criteria set forth above. The record includes the medical records and the testimony from the two hearings. The testimony from Dr. Shoenfeld and Dr. Ward was helpful in explaining the significance of Ms. Shapiro’s signs and symptoms.

B. Findings of Fact

1. Before Ms. Shapiro Received the First Dose of the Hepatitis B Vaccine on April 12, 1992

Ms. Shapiro was born in 1950. Exhibit 4 at 5. She has a history of allergies and mild asthma. Exhibit 6 at 25-26. Her family history includes her mother and sister, who were diagnosed with inflammatory arthritis, and a daughter, who was diagnosed with hyperthyroidism / hypothyroidism in September 1994 at age 16. Id. at 26.

When Ms. Shapiro was 20 years old, she developed a rash shaped like a butterfly. Id. at 25. This type of rash is frequently seen with people who suffer from SLE. The rash lasted for one week, disappearing without treatment. Id. at 57.

Ms. Shapiro maintains that she was “very healthy” prior to 1992. Tr. 14-15; tr. 133; exhibit 39 ¶ 4. Her experts assume this assertion is accurate. Exhibit 28 at 2 (Dr. Bellanti), exhibit 53 at 2 (Dr. Shoenfeld). A record created much closer in time supports a different finding. Exhibit 8 at 10-12.

A preponderance of evidence supports a finding that Ms. Shapiro was having health problems before 1992. In April 1993, Ms. Shapiro saw a gastroenterologist, Dr. Ginsberg, who obtained a history from her.

Dr. Ginsberg’s record dates the onset of Ms. Shapiro’s condition to “about October of 1991.” He notes that Ms. Shapiro experienced progressively worsening constipation, weight gain, and prolonged menstrual periods during the following year. Dr. Ginsberg also recounts that Ms. Shapiro developed palpitations, lightheadedness, and a slow pulse rate (although he does not indicate when she develops these symptoms). Exhibit 8 at 10.

Thus, there is a conflict between Dr. Ginsberg’s record and Ms. Shapiro’s affidavit. Dr. Ginsberg’s 1993 note records that she was having constipation and other problems since October 1991. In contrast, Ms. Shapiro stated that before

1992, she was “very healthy.” Exhibit 39 ¶ 4. Ms. Shapiro made this assertion in 2006, which is more than 10 years after the events in question. Ms. Shapiro has not persuasively explained why her recollection of these distant events is more accurate than the information she provided to Dr. Ginsberg in 1993.⁵ Given the circumstances, Dr. Ginsberg’s record is more probative. See Burns, 3 F.3d at 417; Cucuras, 993 F.2d at 1528.

As discussed below, the finding that a preponderance of evidence shows that Ms. Shapiro suffered constipation, weight gain, and menstrual irregularities in 1991 is very important to resolving her thyroid claim. The experts explained the significance of menstrual irregularities, constipation, and weight gain. Dr. Ward stated that menstrual irregularities, constipation, and weight gain, are common symptoms for hypothyroidism. According to Dr. Ward, these symptoms could have been “abstracted from a textbook description of hypothyroidism.” Exhibit I at 3; accord tr. 285; exhibit E, tab 18 (Vaidya) at 286 (listing presenting symptoms of hypothyroidism). Dr. Shoenfeld, like Dr. Ward, agrees that Ms. Shapiro’s initial symptoms were indicative of a hypothyroid condition. Tr. 175.

2. Time between the First and Second Doses (April 13, 1992 through September 20, 1992)

In April 1992, Ms. Shapiro was working as a pediatric nurse practitioner. OSHA regulations suggested that she receive the hepatitis B vaccinations. Tr. 23; exhibit 1 at 1; see 56 Fed. Reg. 64004, 64179 (Dec. 6, 1991) codified at 29 C.F.R. § 1910.1030(f)(1)(I) (1992) (regulation of Occupational Safety and Health Administration recommending that health care workers receive the hepatitis B vaccine). Ms. Shapiro received the first dose of the hepatitis B vaccine on April 13, 1992. Exhibit 39, exhibit 52, exhibit 86.

On April 29, 1992, Ms. Shapiro saw her gynecologist, Dr. Sylvan Frieman. Although Dr. Frieman’s records are difficult to read, it appears he recorded that

⁵ The finding that Ms. Shapiro’s testimony is not accurate should not be interpreted as a suggestion that Ms. Shapiro deliberately was dishonest. Instead, the passage of time is likely to have mixed the sequence of events in Ms. Shapiro’s recollection. See Cedillo v. Sec’y of Health & Human Servs., No. 98-916V, 2009 WL 331968, at *98-100 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), motion for review denied, 89 Fed. Cl. 158 (2009), aff’d 617 F.3d 1328 (Fed. Cir. 2010); Grace v. Sec’y of Health & Human Servs., No. redacted, 2006 WL 3499511, at *4 (Fed. Cl. Spec. Mstr. Nov. 30, 2006).

Ms. Shapiro had abdominal bloating and weight gain. Exhibit 110 at 3. Ms. Shapiro attempted to fill the gap created by the illegibility in Dr. Frieman's records by testifying. Ms. Shapiro stated that she saw Dr. Frieman for irritability, constipation, and a change in menses approximately two weeks after receiving her first hepatitis B vaccination.⁶ Exhibit 39 ¶ 6; tr. 23-27.

Ms. Shapiro also obtained a typewritten letter from Dr. Frieman in 2001, which recounts an office visit with Ms. Shapiro on April 29, 1992. Dr. Frieman states that Ms. Shapiro had mild complaints, including unusual irritability. Exhibit 1 at 1; tr. 25.

Dr. Ginsberg's record, which notes weight gain, constipation, and prolonged menstrual periods since October 1991, supports Ms. Shapiro's testimony and Dr. Frieman's records regarding the symptoms Ms. Shapiro experienced. However, Dr. Ginsberg's record does not support Ms. Shapiro's or Dr. Frieman's recollection of the onset of these symptoms. Instead, the evidence preponderates in favor of finding that these symptoms did not just begin after her first vaccination in April 1992, but instead, were symptoms she experienced since about October 1991.

Ms. Shapiro also testified that she recalls experiencing jaw pain shortly after the first vaccination and calling her dentist, Dr. Minch. Tr. 23-24. Dr. Minch notes, in a letter dated August 14, 2001, that Ms. Shapiro experienced jaw pain on September 22, 1992, February 23, 1993, and October 12, 1993. Exhibit 12 at 2. The contemporaneous medical records of Dr. Minch, however, do not reflect this. *Id.* at 2-7. Further, these dates occur after Ms. Shapiro's second and third vaccinations, which is in contrast to Ms. Shapiro's testimony that she began experiencing jaw pain after her first vaccination. It is difficult to credit Dr. Minch's note of jaw pain because it was only recalled in a letter written nine years later. *See Cucuras*, 993 F.2d at 1528. Therefore, the weight of the evidence does not support crediting Ms. Shapiro's claim of jaw pain.

⁶ Dr. Shoenfeld assumes that Ms. Shapiro experienced both constipation and palpitations after her first vaccination (Tr. 175); however, neither the medical records nor Ms. Shapiro's own testimony supports his assumption regarding palpitations. Ms. Shapiro reported in her affidavit and testified that she experienced palpitations after the second vaccination. Exhibit 39 at ¶ 7; tr. 27. Further, the medical records of Dr. Berg indicate a report of palpitations on November 19, 1992, after the second vaccination. Exhibit 51 at 2. As a result, Dr. Shoenfeld's assumption regarding the occurrence of palpitations after the first vaccination is not credited because it lacks support.

Ostensibly, it appears that before the second dose Ms. Shapiro saw one more doctor, Dr. Ronald Sweren, a dermatologist. Exhibit 3 at 14. But the date of this record is not accurate.⁷

In sum, the record supports a finding that after the first dose of hepatitis B, Ms. Shapiro continued to have menstrual irregularities, constipation, and weight gain. These problems did not begin after the vaccination. Rather, they started before the vaccination and continued.

3. Period between the Second and Third Doses (September 21, 1992 – February 8, 1993)

Ms. Shapiro received the second dose of the hepatitis B vaccine on September 21, 1992. Exhibit 39 ¶ 7, exhibit 52, exhibit 86. Ms. Shapiro describes experiencing a worsening of symptoms, including palpitations, lightheadedness, serious fatigue, and a decreased ability to finish her sentences. Exhibit 39 ¶ 7; tr. 27. Ms. Shapiro's testimony is credited in part because she saw Dr. Richard Berg for these symptoms on October 19, 1992. Exhibit 51 at 2.

Dr. Berg reported that on October 14, 1992, Ms. Shapiro awakened with an intense headache and neckache that worsened as the day progressed. She felt lightheaded and sweaty. Her heartbeat was rapid and irregular. Exhibit 51 at 2. Dr. Berg ordered a test of Ms. Shapiro's thyroid. Ms. Shapiro's thyroid stimulating hormone (TSH) was 66.67 micro IU/ML. A finding of 6.12 micro IU/ML or greater is consistent with hypothyroidism. Exhibit 111 at 5. Because her result was more than ten times a normal level, Dr. Berg prescribed Synthroid at 100 micrograms. Exhibit 51 at 2. Synthroid is thyroid replacement therapy. Tr. 289.

About one month later, Ms. Shapiro saw Dr. Berg for a follow up visit. Her palpitations and lightheadedness were gone. Exhibit 51 at 2. Her menstrual period was improved. However, she still had some constipation. For this condition, Dr.

⁷ Ms. Shapiro states that she first saw Dr. Sweren in August 1995, because of fungal infections. Tr. 80-81. Here, Ms. Shapiro's recollection of her first visit to Dr. Sweren in 1995 is supported by a prescription note written by Dr. Sweren indicating the patient's first visit in August 1995 (exhibit 85), and by a copy of Ms. Shapiro's invoice from Dr. Sweren's office, also indicating this first visit to be in 1995. Exhibit 108 at 16. Thus, a preponderance of the evidence supports finding that the notation indicating a visit to Dr. Sweren in June 1992 was in error.

Berg recommended more fiber. Id. Ms. Shapiro's thyroid was normal. Exhibit 111 at 16 (laboratory reports from Nov. 19, 1992). She did not return to Dr. Berg for several months.

**4. Period following the third dose
(February 9, 1994 -- July 1994)**

On February 8, 1993, Ms. Shapiro received the third dose of the hepatitis B vaccine. Exhibit 39 (affidavit) ¶ 8, exhibit 52, exhibit 86. Ms. Shapiro reports that after the vaccination, she had "anorexia" and "severe weight loss." Exhibit 39 ¶ 8; tr. 35-36. However, Dr. Ginsberg's history recounts that Ms. Shapiro had been experiencing a "recurrent *increase* in weight" since about February of this year, which was the time she received her third vaccination. Exhibit 8 at 10. This conflict in the evidence is likely not significant. Ms. Shapiro testified that she had been gaining weight prior to taking the Synthroid medication. Tr. 35. This would support Dr. Ginsberg's assertion. And Ms. Shapiro's recollection of weight loss after the third vaccination is supported in Dr. Joyce Burd's history of the patient in July 1994. Dr. Burd notes that during the time that Ms. Shapiro's Synthroid medication was being adjusted, she lost approximately 23 pounds. Exhibit 6 at 25. Therefore, a preponderance of the evidence supports finding that Ms. Shapiro's weight fluctuated around the time of this third vaccination while her dosage of Synthroid was being adjusted.

Weight gain and weight loss are particularly useful when diagnosing a thyroid condition. Weight loss is indicative of hyperthyroidism, and weight gain suggests hypothyroidism. Dorland's at 889, 900. Ms. Shapiro reported weight gain after receiving her first and second vaccinations. Following this third vaccination, she reported weight loss (Tr. 35-36) and experienced weight fluctuations in response to changes in dosing of her thyroid medication. Tr. 288-89; see also exhibit 51 at 3-4.

In March 1993, Ms. Shapiro returned to Dr. Berg with complaints of worsening symptoms, including palpitations, nausea that lasted all day, and abdominal pain. Exhibit 39 ¶ 8; tr. 37-38. Dr. Berg's records support crediting Ms. Shapiro's recollection. Exhibit 51 at 3. In response, Dr. Berg adjusted Ms. Shapiro's thyroid medication. Id.; exhibit 39 ¶ 9; see also exhibit 111 at 21 (various thyroid tests were within normal range) at 25 (showing thyroid stimulating hormone was at the low end of the normal range). Dr. Berg also referred Ms. Shapiro to Dr. Frieman. Exhibit 51 at 3.

In April 1993, Ms. Shapiro continued experiencing nausea and discomfort in her abdomen. Dr. Ginsberg could not identify a cause for these problems. Exhibit 8 at 10. A CT scan of her abdomen was normal. Exhibit 112 at 6. An upper endoscopy was performed, resulting in a diagnosis of gastritis, which is inflammation of the stomach. Exhibit 8 at 13-14; Dorland's at 757.

In April, May, June and July 1993, Ms. Shapiro saw Dr. Berg five times. In response to various complaints including joint pain, Dr. Berg adjusted her thyroid medication. Exhibit 51 at 3-4; see also exhibit 109 at 3 (labs from March 30, 1993), exhibit 112 at 21 (labs from May 24, 1993).

Ms. Shapiro reported her symptoms after the vaccinations to the manufacturer of the vaccine and the Vaccine Adverse Event Reporting System (VAERS) in July 1993. She reported weight loss, lightheadedness, palpitations, weight on chest, fatigue, and nausea, among others. Exhibit 27 at 5. Problems such as weight gain and a difficulty finding her words were mentioned in an appendix to her July 1993 VAERS report. Exhibit 118 at 5; see also tr. 369.

Also in July 1993, Ms. Shapiro saw a urologist, Dr. Schonwald, complaining of blood in her urine. Tr. 40-41. (The medical term for blood in urine is "hematuria." Dorland's at 844.) Dr. Schonwald performed a cystoscopy (examination of cells, Dorland's at 470) on Ms. Shapiro's bladder. The test results were normal. Exhibit 17 at 17-19. Ms. Shapiro has not identified any medical record that confirms that she had blood in her urine.

Relying on Ms. Shapiro's testimony, Dr. Shoenfeld opines that blood in Ms. Shapiro's urine is a strong indicator that Ms. Shapiro was no longer suffering from a thyroid autoimmune disease, but that it indicates that she had progressed to suffering from a second autoimmune disease. Dr. Shoenfeld states that blood in Ms. Shapiro's urine is a symptom that does not belong to an autoimmune thyroid disease. Tr. 178-79.

Because Ms. Shapiro did see Dr. Schonwald for this complaint, there is some credibility to her claim that she had, or thought she had, blood in her urine.⁸ However, Dr. Schonwald's examination in response to Ms. Shapiro's complaint produced normal results. Dr. Schonwald did not recommend further treatment or follow-up care. Exhibit 17 at 19. Accordingly, a preponderance of the evidence

⁸ Citing Dr. Shoenfeld's testimony on direct examination, Ms. Shapiro argues her hematuria was noted by several of her doctors. However, neither Ms. Shapiro's brief nor Dr. Shoenfeld identified these physicians. See Pet'r Post-Hearing Br. at 28; tr. 179.

does not support a finding that the presence of blood in Ms. Shapiro's urine was a continuing symptom.

On September 28, 1993, Ms. Shapiro saw Dr. Berg again. She reported feeling "better" with "good appetite." However, she also informed Dr. Berg that she was having constipation, explosive diarrhea, and irregular and long menstrual periods. It also appears that she had joint pain in her hands, although the doctor's handwriting is difficult to read. Exhibit 51 at 4; accord exhibit 39 ¶ 15; tr. 42. On this date, tests of her thyroid produced results within the normal limits. Exhibit 112-3 at 68, 70. Whether Dr. Berg recommended any medical treatment is difficult to determine due to his handwriting. Exhibit 51 at 4.

Ms. Shapiro was feeling better in the fall of 1993. Exhibit 39 ¶ 15; exhibit 6 at 26. After Dr. Berg adjusted Ms. Shapiro's thyroid medication, her symptoms abated when a proper dosage was found. Further evidence that Ms. Shapiro was improved because of the Synthroid medication is the fact that she did not see a doctor for a period of approximately 10 months, until July 1994. Exhibit 51 at 4-5; exhibit I at 10.

5. July 1994 – Present

The next medical appointment was on July 7, 1994, with Dr. Berg. The absence of medical records from September 1993 to this date indicates that this was Ms. Shapiro's first visit with a doctor in 10 months. Dr. Berg's records from this visit indicate that two weeks earlier, all her joints were aching; however, there was no redness and no swelling in her joints. Dr. Berg also performed tests on Ms. Shapiro, one which indicated that Ms. Shapiro had a positive antinuclear antibody (ANA). This result prompted Dr. Berg to refer Ms. Shapiro to Dr. Burd, a rheumatologist. Exhibit 51 at 4-5; see also exhibit 112-3 at 76-77 (laboratory results reported July 15, 1994).

With the referral to Dr. Burd, Ms. Shapiro's interaction with various doctors happened much more frequently. Medical records were created contemporaneously with the events being described in those records. The parties do not dispute the accuracy of records created after July 1994 to the extent that the records are describing contemporaneous events.

On July 28, 1994, Ms. Shapiro saw Dr. Burd, primarily because she was having diffuse arthralgias (pain in a joint, Dorland's at 149). Dr. Burd ordered various tests. Exhibit 6 at 25.

Approximately one month later, Ms. Shapiro returned to Dr. Burd. Ms. Shapiro's ANA was positive (exhibit 6 at 27). ANAs can be used to diagnose SLE. If the ANA test is positive, other studies must be done to confirm a diagnosis. Kathleen D. Pagana and Timothy J. Pagana, Mosby's Manual of Diagnostic and Laboratory Tests, 86 (2d ed. 2002).

Ms. Shapiro's Smith-antibody was negative. Exhibit 112-3 at 52-54 (laboratory report dated July 15, 1994). The Smith-antibody test is positive in approximately 30 percent of people with SLE. Pagana, Mosby's Manual 78, 79. The laboratory values for thyroid were within normal limits. Exhibit 112-3 at 56.

Dr. Burd stated that Ms. Shapiro was suffering from an autoimmune disorder, probably mild SLE. Dr. Burd further stated that she was not aware of the hepatitis B vaccine causing SLE. Exhibit 6 at 28-29.⁹

On November 1, 1994, Ms. Shapiro saw Dr. Drachman, a neurologist at Johns Hopkins University. Dr. Drachman obtained a history, which states, in part, that Ms. Shapiro was in "her normal state of health until April 1992, when she had the first of three hepatitis B immunizations." Exhibit 10 at 82. (This report is not accurate because Dr. Ginsberg's earlier report places the onset of her constipation, weight gain and menstrual irregularities to October 1991. Exhibit 8 at 10). Dr. Drachman also examined Ms. Shapiro. Dr. Drachman stated that Ms. Shapiro's positive ANA and other problems suggested an "autoimmune disorder." Dr. Drachman ruled out an inflammatory myopathy and multiple sclerosis. He ordered additional tests and recommended consulting another rheumatologist. Exhibit 10 at 82-84; tr. 48.¹⁰

⁹ Later, Dr. Burd joined with Ms. Shapiro to write a letter, recommending additional study to assess whether immunizations cause SLE. Exhibit 30 (Elizabeth Shapiro & Joyce Kopicky Burd, "Comment on the Article 'Can Immunization Precipitate Connective Tissue Disease? Report of 5 Cases of Systemic Lupus Erythematosus and Review of the Literature,'" 30 No. 3 Seminars in Arthritis and Rheumatism, 215 (2000)).

¹⁰ Citing only this record from Dr. Drachman, Ms. Shapiro argues that "her contemporaneous reports as to her reactions to the hepatitis B vaccinations to her numerous doctors are consistent." Pet'r Reply at 5.

The sincerity of Ms. Shapiro's belief that the hepatitis B vaccines caused her an injury has never been doubted. But, Ms. Shapiro's good faith and sincere belief is not determinative. See 42 U.S.C. § 300aa – 13(a)(1) (stating that a special master may not award compensation "on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion."). Although Ms.

After 1994, Ms. Shapiro continued to experience problems with her health. The details of these events are generally not relevant to determining whether she experienced an adverse reaction to the hepatitis B vaccinations. The parties agreed that any determination about the sequella to any adverse reaction could be made during the damages phase of the case. Tr. 6.

Ms. Shapiro maintains that she suffers from SLE and seeks compensation for this condition. Pet'r Post-Hearing Br. at 19. Thus, only the records discussing SLE are summarized. In support of the claim that she has SLE, Dr. Shoenfeld testified that Ms. Shapiro's treating doctors diagnosed her with SLE. Tr. 185. Although Dr. Shoenfeld did not identify these doctors, Ms. Shapiro cites three records. Pet'r Post-Hearing Br. at 21-22 (citing exhibit 5 at 23-24, 54).

The first two records cited by Ms. Shapiro are progress notes created in 1999 by Dr. David McGinnis.¹¹ Exhibit 5 at 23-24. Although Dr. McGinnis's impressions state that Ms. Shapiro has a "history of lupus," Dr. McGinnis's progress notes otherwise provide little helpful information. The records cited by Ms. Shapiro do not mention anything about onset of this condition.

The third record cited by Ms. Shapiro as establishing her SLE is a medical record from Dr. Michelle Petri. Dr. Petri's evaluation of Ms. Shapiro took place on March 22, 2002, in response to a referral from Dr. McGinnis. In this record, Dr. Petri notes that Ms. Shapiro's SLE "appears to be in good control." Exhibit 5 at 53-54. Dr. Petri's notation supports a finding that Ms. Shapiro was suffering from SLE in 2002. However her record, like those of Dr. McGinnis, does not indicate onset of Ms. Shapiro's SLE.

When Dr. Shoenfeld was questioned about the onset of Ms. Shapiro's SLE at trial, he did not directly answer the question. Dr. Shoenfeld testified that as an

Shapiro's training as a pediatric nurse practitioner makes her views more probative than the views of a person without any medical training, Ms. Shapiro has not claimed that her opinion constitutes a "medical opinion."

¹¹ Although Ms. Shapiro cited to pages 23-24 of exhibit 5, an independent review of the medical records indicates that the same record appears as pages 145 and 147 of exhibit 11. Exhibit 11 is more useful because exhibit 11 contains numerous records from Dr. McGinnis, providing a context for the statements cited in Ms. Shapiro's brief. Exhibit 11 shows that Dr. McGinnis works in the same practice as Dr. Burd, see exhibit 11 at 130-32, and that Dr. Burd began treating Ms. Shapiro in 1994, exhibit 11 at 104.

“autoimmunologist,” he would have diagnosed Ms. Shapiro with SLE because of her thyroid problems, her family history of arthritis, the joint pains, and hematuria she experienced. He testified that he would have started Ms. Shapiro on medication for SLE shortly after she received her third vaccination, yet he admits that treatment would only be based on a suspicion of SLE. Dr. Shoenfeld explains that it is easier to look back and make a diagnosis of SLE while, at the time, one could not “definitively say SLE.” Tr. 220-23.

Dr. Shoenfeld’s testimony is not particularly helpful when determining the onset of Ms. Shapiro’s SLE, nor are the medical records cited by Ms. Shapiro. However, an independent evaluation of the medical records uncovers Dr. Burd’s record identifying Ms. Shapiro as suffering from an autoimmune condition, “probably SLE,” in September 1994. Although Ms. Shapiro does not make this argument herself, a preponderance of the evidence supports finding that onset of Ms. Shapiro’s SLE was September 1994.¹²

At the time of the hearing, Ms. Shapiro testified that her life has changed because of her illness. Ordinary tasks, such as entertaining and grocery shopping, have become difficult, while activities such as cleaning, cooking, carpooling, gardening and playing the piano have become “virtually impossible.” Tr. 16-17. Ms. Shapiro remains on medications to manage her symptoms. Tr. 76.

III. Standards for Adjudication

To receive compensation under the Program, Ms. Shapiro must prove either: (1) that she suffered a “Table Injury”--*i.e.*, an injury falling within the Vaccine Injury Table – corresponding to the hepatitis B vaccination, or (2) that she suffered an injury that was actually caused by the hepatitis B vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec’y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, no injuries are associated with the hepatitis B vaccine on the Vaccine Injury Table. Thus, Ms. Shapiro must prove causation in fact.

When a petitioner proceeds on a causation-in-fact theory, a petitioner must establish three elements. The petitioner’s

¹² It is not possible to date the beginning of Ms. Shapiro’s SLE with absolute certainty, but absolute certainty is not required. Andreu v. Sec’y of Health & Human Servs., 569 F.3d 1367, 1380 (Fed. Cir. 2009); Bunting v. Sec’y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For the elements that petitioners are required to prove, their burden of proof is a preponderance of the evidence. 42 U.S.C. § 300aa–13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). 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 (2000); 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). In this regard, “close calls regarding causation are resolved in favor of injured claimants.” Althen, 418 F.3d at 1280.

IV. Analysis

Ms. Shapiro claims that the hepatitis B vaccination caused her to develop an autoimmune thyroid condition and SLE. The reasons why Ms. Shapiro is not entitled to compensation for the thyroid condition and SLE will be explained separately below.

A. Thyroid Condition

The first step in deciding Ms. Shapiro’s claim that the hepatitis B vaccine caused her to suffer a thyroid condition is to determine when her thyroid problems began. Dr. Shoenfeld opines that the hepatitis B vaccinations caused Ms. Shapiro

to develop an autoimmune thyroid condition. Tr. 177-79. In contrast, respondent's expert, Dr. Ward, concludes that Ms. Shapiro had an erratic thyroid condition that likely began before she received her first vaccination. Exhibit C at 10-11.

The experts agreed that gaining weight, having constipation, and having menstrual irregularities are symptoms of a hypothyroid condition. Tr. 175 (Dr. Shoenfeld); exhibit I at 3 (Dr. Ward). When Ms. Shapiro started having these problems is a question of fact. Here, a preponderance of the evidence supports a finding that Ms. Shapiro was gaining weight, having constipation, and having menstrual problems beginning around October 1991. The evidence supporting this finding is summarized in section II.B.¹³ Thus, a preponderance of evidence supports a finding that Ms. Shapiro's thyroid problems began in approximately October 1991.

A finding that Ms. Shapiro's thyroid problems began before she received the hepatitis B vaccine resolves Ms. Shapiro's claim that the hepatitis B vaccine caused her thyroid condition. Because Ms. Shapiro was afflicted with a thyroid condition before she received the hepatitis B vaccine, the vaccine could not have caused the disease. See Shalala v. Whitecotton, 514 U.S. 268, 274 (1995) (stating "There cannot be two first symptoms or onsets of the same injury.").¹⁴

B. Systemic Lupus Erythematosus

Dr. Shoenfeld also opines that after Ms. Shapiro received the second and third doses of the vaccine, there was "ignition" of a second autoimmune disease, SLE. Id. at 178-179. To prevail on this claim, one of Ms. Shapiro's burdens is to

¹³ Dr. Shoenfeld's assumption that Ms. Shapiro correctly stated that she began gaining weight after the first dose of the hepatitis B vaccine does not validate Ms. Shapiro's assertion. Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1574 (Fed. Cir. 1993).

¹⁴ Given that Ms. Shapiro's thyroid condition could not have been caused by the hepatitis B vaccine, an analysis of the three-factor test set forth in Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005), is not necessary.

Further, neither Ms. Shapiro nor her experts asserted a claim that the hepatitis B vaccine significantly aggravated her thyroid condition. 42 U.S.C. § 300aa-11(c)(ii)(I). Because this theory was not addressed by Ms. Shapiro, it is not considered now. See Vaccine Rule 8(f)(1).

establish an appropriate temporal relationship. For the reasons discussed below, Ms. Shapiro has not met this burden.

Petitioners are required to establish a “showing of a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278. When petitioners fail to establish this element, they are not entitled to compensation.¹⁵ Pafford v. Sec’y of Health & Human Servs., 64 Fed. Cl. 19, 29-30 (2005), aff’d, 451 F.3d 1352, 1358-59 (Fed. Cir. 2006). The Federal Circuit has elaborated that the third prong of the Althen test requires “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” Bazan v. Sec’y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). Thus, the two components of this prong are (a) the timeframe for which it is “medically acceptable to infer causation,” and (b) the onset of the condition for which petitioner seeks compensation.

1. The Medically Appropriate Temporal Relationship

For the timeframe for which it is “medically acceptable to infer causation,” Dr. Shoenfeld proposes three different times (a) two to three weeks, (b) six to eight months, and (c) an incubation period of 10 years. Tr. 197-98; tr. 228-29.

A time frame within three weeks after exposure to an antigen is the only time frame supported. An article coauthored by Dr. Shoenfeld reports instances in which five healthy patients received a combination of vaccines, including the hepatitis B vaccine. These patients then developed SLE within three weeks after the secondary immunization. The article states that this temporal relationship “makes it plausible that the vaccination was the trigger factor for the onset of the disease (or symptoms).”¹⁶ Exhibit 59 (A. Aron-Maor & Y. Shoenfeld, Vaccination

¹⁵ Because the third Althen prong is dispositive, no finding is made for the first and second prongs of Althen.

¹⁶ This article acknowledges that while a temporal relationship has been noticed, a causal relationship between the hepatitis B vaccine and SLE has not been found. Exhibit 59. A temporal relationship alone is not enough to support Ms. Shapiro’s claim for compensation for her SLE. Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1147 (Fed. Cir. 1992).

and systemic lupus erythematosus: the bidirectional dilemmas, 10 *Lupus* 237, 238 (2001)).

Publication in a peer-reviewed journal suggests that the medical community is interested in learning about cases of SLE within three weeks of immunization. Further, Dr. Ward does not specifically contradict Dr. Shoenfeld's assertion that two to three weeks is an appropriate interval from which causation may be inferred as it relates to SLE.¹⁷ Therefore, for purposes of analyzing whether Ms. Shapiro's evidence satisfies Althen prong 3, a time frame within three weeks after the exposure to an antigen is supported.¹⁸

In contrast, no persuasive evidence supports crediting a temporal relationship of six months or an incubation period of ten years. Dr. Ward states that Dr. Shoenfeld's contention that the presentation of SLE could be months or even years after exposure to the vaccine "runs completely contrary to the medical evidence." Tr. 293; see also Resp't Post-Hearing Br. at 24. In another case, when Dr. Shoenfeld proposed a similarly lengthy amount of time, his testimony was rejected. Hennessey v. Sec'y of Health & Human Servs., 91 Fed. Cl. 126, 142 ("In effect, Dr. Shoenfeld's testimony renders Althen's third prong a nullity. Under his theory, nearly any conceivable timing could qualify as an appropriate temporal relationship.").

¹⁷ Dr. Ward does counter Dr. Shoenfeld's discussion of an appropriate temporal relationship between the administration of the first dose of the hepatitis B vaccine and the discovery of Ms. Shapiro's thyroid disease. Exhibit I at 3, 11; tr. 291-92; tr. 353.

¹⁸ This reliance on the Aron-Maor and Shoenfeld article to establish an appropriate temporal relationship should not be interpreted as a finding that this article supports a finding that the hepatitis B vaccine can cause SLE. The Aron-Maor and Shoenfeld article is a collection of case reports.

Case reports can be useful as a prompt for doctors to begin investigating a possible causal relationship. Jackson v. Sec'y of Health & Human Servs., No. 05-277V, 2006 WL 5624402, at *5-6 (Fed. Cl. Spec. Mstr. Jan. 24, 2007); see also tr. 199. By themselves, case reports are generally an unpersuasive method to establish causation. Tr. 253-58, tr. 330, tr. 367-68; see also McClain v. Metabolife Intern., Inc., 401 F.3d 1233, 1253 (11th Cir. 2005); Gastetter v. Novartis Pharmaceuticals Corp., 252 F.3d 986, 989-90 (8th Cir. 2001); but see tr. 326-27 (describing a case report of challenge-rechallenge).

For these reasons, a preponderance of the evidence supports finding that a medically acceptable time frame for symptoms of SLE is within three weeks after an exposure to the hepatitis B vaccine. The next question is whether Ms. Shapiro experienced any symptoms of SLE within that time frame.

2. Ms. Shapiro's Signs And Symptoms Within Three Weeks After Doses Two And Three Of The Vaccine

As indicated in Bazan, 539 F.3d at 1352, in addition to showing the “medically appropriate” interval between vaccination and injury, petitioners must establish that their problems started within this interval. The operative dates in Ms. Shapiro’s case are September 21, 1992 and February 8, 1993, the dates of the second and third doses. To be consistent with Dr. Shoenfeld’s theory, Ms. Shapiro must have developed problems of SLE within three weeks of these dates.

Dr. Shoenfeld testified that there was “ignition” of Ms. Shapiro’s SLE when she had the joint pains and the hematuria. Tr. 178; tr. 220-21 (Dr. Shoenfeld stating that Ms. Shapiro’s “first two symptoms, the joint pains and the hematuria, appeared immediately just heralding the disease and then slowly...she accumulated all the system involvement...that she fulfilled all the criteria of the disease.”). However, neither the joint pains nor the hematuria falls within the medically appropriate interval.

The first symptom of SLE that Dr. Shoenfeld associates with Ms. Shapiro’s SLE is joint pain. The earliest reference to joint pain in Ms. Shapiro’s brief is July 28, 1993. Pet’r Post-Hearing Br. at 6. At this time, Ms. Shapiro went to see Dr. Berg with complaints of intermittent sharp pain in her hands and feet joints. Exhibit 51 at 4. These symptoms occurred months after her third dose of the vaccine. Thus, Ms. Shapiro’s joint pain does not fall within the period expected by Dr. Shoenfeld.

The second sign of SLE that Dr. Shoenfeld associates with Ms. Shapiro’s SLE is hematuria. Dr. Shoenfeld opines that blood in Ms. Shapiro’s urine (hematuria) indicates that she had progressed to suffering from a second autoimmune disease, SLE. Tr. 178-79. This sign did not appear within the medically acceptable time frame of three weeks following exposure to the antigen. Ms. Shapiro saw a urologist for this complaint in July 1993. Further, a preponderance of the evidence supported finding that hematuria was not a lingering symptom. See section II.B.4. Thus, even if blood in Ms. Shapiro’s urine were credited (and there is some doubt), the report of hematuria in July 1993 falls outside the medically appropriate temporal interval.

Joint pains and hematuria are the two problems identified by Dr. Shoenfeld as the initial manifestations of Ms. Shapiro's SLE. As discussed above, these problems do not advance Ms. Shapiro's proof on Althen prong 3 because they did not fall within the time for which an inference of causation is appropriate. In addition to these two problems, Ms. Shapiro argues that her irritability was a symptom of SLE. For this proposition, Ms. Shapiro relies upon the testimony of Dr. Ward, not Dr. Shoenfeld. Pet'r Br. at 23 (citing tr. 344). Ms. Shapiro's citation takes a portion of Dr. Ward's testimony out of context. While Dr. Ward testified that irritability may be a symptom of SLE (tr. 344), he also stated that irritability is a "textbook" symptom of hypothyroidism. Tr. 286.

Dr. Ward states that all of Ms. Shapiro's symptoms prior to and immediately following her first and second doses of the hepatitis B vaccine are compatible with hypothyroidism. Exhibit I at 7. Ms. Shapiro was diagnosed with hypothyroidism approximately one month after receiving her second dose and started on Synthroid. See section II.B.2.

Dr. Ward additionally states that most of her symptoms around the time of her third dose can be explained by "fluctuations in her thyroid status (and the development of her various intra-abdominal problems)." Id. at 7, 10 (stating "Mrs. Shapiro's thyroid status did not suddenly normalize once she began replacement therapy, and there were several changes of her replacement therapy in the weeks and months immediately following her 3rd dose of HBV...This is well-documented in the medical records."). Dr. Ward's opinion is sound because following Ms. Shapiro's third dose on February 8, 1993, her weight fluctuated in response to changes in doses of her thyroid medication. She also experienced palpitations, lightheadedness, and severe fatigue, which resulted in Dr. Berg adjusting her thyroid medication. See section II.B.4. By the fall of 1993, Ms. Shapiro's symptoms seemed to alleviate when the proper dosage was found. This evidence supports crediting Dr. Ward's conclusion that Ms. Shapiro's symptoms around the time of her third dose can be attributed to an erratic thyroid condition and the changes in dosage of her Synthroid medication.

For these reasons, Ms. Shapiro fails to meet the third prong of Althen. Because Ms. Shapiro failed to establish Althen prong 3, she is not entitled to compensation for SLE. Pafford, 64 Fed. Cl. at 29-30.

V. Conclusion

Ms. Shapiro presented a theory for compensation asserting that her thyroid disease began after her April 1992 hepatitis B vaccination. This theory is not supported because a preponderance of the evidence establishes that Ms. Shapiro suffered from a thyroid dysfunction before she received her first vaccination in April 1992. Because Ms. Shapiro's thyroid problems began before she received her first hepatitis B vaccination, the vaccine did not cause her thyroid condition.

Ms. Shapiro's second theory for compensation asserted that she developed SLE within three weeks after her second dose or third dose of the hepatitis B vaccine. Ms. Shapiro has established that a medically appropriate interval for the development of SLE is within three weeks of a vaccination. But, Ms. Shapiro did not experience problems linked to SLE within three weeks following her second or third dose. Although the record shows that Ms. Shapiro may have developed SLE, this onset was outside the time expected by medical science. See Pafford, 451 F.3d at 1358 ("without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside the time in which scientific or epidemiological evidence would expect an onset of harm.").

Therefore, Ms. Shapiro is not entitled to compensation for her thyroid condition or SLE. The Clerk's Office is instructed to enter judgment for respondent unless a motion for review is filed.

IT IS SO ORDERED.

S/ Christian J. Moran

Christian J. Moran
Special Master