

# In The United States Court of Federal Claims

No. 99-552V

Filed: June 20, 2012

Reissued: September 13, 2012<sup>1</sup>

ELIZABETH SHAPIRO,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

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\* Vaccine case; Petition for review; Hepatitis-  
\* B vaccination; Standard of review;  
\* Hypothyroidism; *Althen*; Failure to establish  
\* causation; Failure to establish proximate  
\* temporal relationship between vaccine and  
\* autoimmune thyroid disease; Motion for  
\* reconsideration under RCFC 59; Failure to  
\* show that prior findings were wrong, let  
\* alone manifestly unjust; Motions for review  
\* and for reconsideration denied.  
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## OPINION

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*Clifford John Shoemaker*, Shoemaker and Associates, Vienna, VA, for petitioner.

*Heather Lynn Pearlman*, United States Department of Justice, Washington, D.C., with whom was Assistant Attorney General *Tony West*, for respondent.

### **ALLEGRA, Judge:**

Petitioner, Elizabeth Shapiro, seeks review of a decision issued by Special Master Christian Moran denying her petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to 300aa-34 (2006), alleging that she suffers from hypothyroidism and Systemic Lupus Erythematosus (SLE) as a result of hepatitis-B vaccinations that she received. Initially, the

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<sup>1</sup> An unredacted version of this opinion was issued under seal on June 20, 2012. The parties were given an opportunity to propose redactions, but no such proposals were made. Nonetheless, the court has incorporated some minor changes into this opinion.

Special Master denied compensation, finding that petitioner's illnesses were not caused by the hepatitis-B vaccinations. *Shapiro v. Sec'y of Health and Human Servs.*, 2011 WL 1897650 (Fed. Cl. Apr. 27, 2011) (*Shapiro I*). This court affirmed the Special Master's findings regarding the SLE claim, but remanded the case for further consideration of petitioner's thyroid claim. *Shapiro v. Sec'y of Health and Human Servs.*, 101 Fed. Cl. 532 (2011) (*Shapiro II*). After further consideration, the Special Master issued a decision denying compensation on the thyroid claim. *Shapiro v. Sec'y of Health and Human Servs.*, 2012 WL 273686 (Fed. Cl. Jan. 10, 2012) (*Shapiro III*). Petitioner now moves for review of this decision, as well as for reconsideration of the denial of her SLE claim. For the reasons that follow, however, the court **DENIES** both motions.

## I. BACKGROUND

A brief recitation of the facts provides necessary context.<sup>2</sup>

Petitioner was born in 1950 and is a nurse-practitioner. She has three children and her husband is a pediatrician. The record contains no contemporaneous medical records suggesting that petitioner had either of the illnesses in question prior to receiving her first hepatitis-B vaccination in 1992. Her only medical visits before those vaccinations were for routine checkups.

On April 13, 1992, petitioner received the first of three hepatitis-B vaccinations. On April 29, 1992, she visited Dr. Sylvan Frieman and reported abdominal bloating and weight gain. Dr. Frieman's records do not reflect when these symptoms began.

On September 21, 1992, petitioner received her second hepatitis-B vaccination. On October 19, 1992, petitioner visited Dr. Richard Berg, an internist and infectious disease specialist, complaining of a five-day history of severe headache and neck ache; lightheadedness; a rapid, irregular heartbeat; and an extended menstrual period. That same day, testing revealed that petitioner's thyroid stimulating hormone (TSH) was ten times the normal level, indicative of hypothyroidism. On October 21, 1992, Dr. Berg prescribed synthroid to treat petitioner's hypothyroidism. About a month later, petitioner's palpitations and lightheadedness had abated and her menstrual period had improved.

On February 8, 1993, petitioner received her third and final hepatitis-B vaccination. She returned to Dr. Berg twice in March of 1993, complaining of worsening symptoms, and reporting palpitations, nausea and abdominal pain. Petitioner's weight fluctuated during this period, likely as the result of her thyroid condition and treatment. Dr. Berg adjusted petitioner's dosage of synthroid and referred her back to Dr. Frieman, as well as to a new doctor, Dr. Ronald L. Ginsberg, a gastroenterologist. Petitioner visited Dr. Ginsberg in April of 1993, complaining of constipation, weight gain, prolonged menstrual periods, palpitations and lightheadedness.

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<sup>2</sup> As the basic facts here have not changed significantly, the court's recitation of the background facts here draws from its earlier opinion in *Shapiro II*.

Petitioner continued to experience nausea and discomfort in her abdomen. Dr. Ginsberg ordered a CT scan of her abdomen, which was normal. An upper endoscopy was then performed, resulting in a diagnosis of gastritis. Five times from April through July of 1993, petitioner saw Dr. Berg. Dr. Berg readjusted her medication. In July of 1993, petitioner's thyroid tests were normal. On July 23, 1993, she filed an incident report with the Vaccine Adverse Event Reporting System, citing problems such as weight loss, light-headedness, palpitations, weight on chest, fatigue and nausea.

On August 2, 1999, petitioner filed her vaccine petition. Subsequently, she filed several sets of medical records and a number of expert reports. Among the reports was one rendered by Dr. Joseph Bellanti, in June 2006, who opined that Ms. Shapiro's symptoms worsened after each dose of the hepatitis-B vaccination, a causation pattern known as "challenge-rechallenge." Dr. Bellanti opined that this sequence of adverse reactions resulted in the development of SLE. On January 8, 2007, petitioner filed a report by a second expert, Dr. Yehuda Shoenfeld, who serves as the head of the Center for Autoimmune Diseases at Sheba Medical Center, Tel-Aviv University, Israel.<sup>3</sup> Dr. Shoenfeld opined that Ms. Shapiro likely had a genetic predisposition to develop autoimmune diseases and that the hepatitis-B vaccine triggered her autoimmune condition. Dr. Shoenfeld linked the three hepatitis-B vaccinations received by petitioner to her development of thyroid disease and SLE. For its part, respondent provided expert reports from two doctors, Dr. Alan Brenner and Dr. Brian Ward. Both concluded that there was no association between Ms. Shapiro's medical conditions and her receipt of the hepatitis-B vaccine.

On July 30, 2007, the case was reassigned to Special Master Moran. He conducted two hearings in the case – on November 24, 2008, and January 8, 2009, respectively. At the first of these hearings, Ms. Shapiro and Dr. Shoenfeld testified in person; at the second, Dr. Ward testified in person. Subsequent to these hearings, Ms. Shapiro was permitted to file additional evidence and medical literature in support of her case.

On April 27, 2011, the Special Master issued a decision denying petitioner's claim. *Shapiro I*, 2011 WL 1897650. In that decision, he rejected the opinions of petitioner's experts, observing that they had relied on assertions made by Ms. Shapiro that she was healthy prior to 1992. Although Ms. Shapiro had reaffirmed these assertions in affidavits filed in the case, the Special Master concluded that "[a] preponderance of evidence supports a finding that Ms. Shapiro was having health problems before 1992." *Id.* at \*6. In this regard, the Special Master relied heavily on the April 1993 records of petitioner's gastroenterologist, Dr. Ginsberg, finding that his records put the onset of petitioner's hypothyroidism condition to about October of 1991 – before she received the first of the vaccinations in question. The Special Master concluded his brief analysis of the thyroid issue by stating that "[a] finding that Ms. Shapiro's thyroid problems began before she first received the hepatitis B vaccine resolves Ms. Shapiro's claim that the

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<sup>3</sup> As noted by the Special Master in his opinion, Dr. Shoenfeld "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*. *Shapiro I*, 2011 WL 1897650, at \*2.

hepatitis-B vaccine caused her thyroid condition,” adding that “[b]ecause Ms. Shapiro was afflicted with a thyroid condition before she received the hepatitis-B vaccine, the vaccine could not have caused the disease.” *Id.* at 13.

As to Ms. Shapiro’s SLE claim, the Special Master noted that proof of that claim required evidence of a temporal relationship between the administering of the vaccine and the onset of Mr. Shapiro’s SLE symptoms. The Special Master first reviewed the medical literature and Dr. Shoenfeld’s testimony and concluded, based thereupon, that the timeframe in which it was “medically acceptable to infer causation” was two to three weeks, that is to say, this was the period within which exposure to any antigen in the vaccine should have produced symptoms. *Id.* at \*14. The Special Master then found that petitioner’s symptoms did not onset within this interval. He noted that petitioner’s second and third doses of the vaccine were administered on September 21, 1992, and February 8, 1993, respectively. He further noted that the two symptoms that Dr. Shoenfeld testified had heralded the onset of the SLE did not arise until July of 1993 – as documented by medical reports from Drs. Berg and Schonwald – too late to fall within the period expected. The Special Master found, relying upon the expert report of Dr. Ward, that the remainder of the symptoms petitioner experienced “immediately following her first and second doses of the hepatitis B vaccine are compatible with hypothyroidism.” *Id.* Based on these findings, the Special Master concluded that Ms. Shapiro had failed “to establish a ‘showing of a proximate temporal relationship between vaccination and injury.’” *Id.* at \*13 (quoting *Althen v. Sec’y of Health and Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)).<sup>4</sup> On this basis, he found that “Ms. Shapiro is not entitled to compensation for her thyroid condition or SLE.” *Id.*

On May 27, 2011, petitioner filed a motion to review the Special Master’s decision. On October 27, 2011, this court issued an opinion granting, in part, and denying, in part, petitioner’s motion for review. The court vacated the Special Master’s finding that petitioner had suffered from thyroid disease prior to receiving her first vaccination, finding that the Special Master had improperly relied upon a single medical record as a “factual fulcrum on which to leverage his findings.” *Shapiro II*, 101 Fed. Cl. at 537. The court found that the Special Master improperly treated the medical record in question, the October 1993 letter by Dr. Ginsberg, as a

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<sup>4</sup> Regarding petitioner’s SLE claim, the Special Master further observed:

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.

*Shapiro I*, 2011 WL 1897650, at \*16.

contemporaneous medical record, even though it was written years after the symptoms it described and “was in no sense contemporaneous.” *Id.* at 539. What’s more, this court observed, the Special Master’s opinion ignored a statement on the very next page of Dr. Ginsberg’s letter that supported petitioner’s claim that she had acquired her thyroid disease after the first of her vaccinations. *Id.* at 540. Wrote the court, “the Special Master was not at liberty to don blinders to the portion of the letter that contradicted his findings and then to use his selective reading to shred other evidence originating near the same time as the letter.” *Id.* Accordingly, the court remanded the matter to the Special Master to reconsider the record as a whole.

Regarding petitioner’s SLE, the court held that the Special Master had not erred in finding that petitioner had failed to demonstrate a proximate temporal relationship between the vaccination and the onset of her SLE. *Id.* at 542. The court held that the Special Master requirement that symptoms of SLE develop within two to three weeks of her vaccinations was reasonable and supported by the record. It further found that the record supported the Special Master’s finding that petitioner had “failed to demonstrate that she had SLE symptoms during the accepted temporal causation period.” *Id.* at 542-43. In short, “the denial of compensation in this case . . . was not the result of a misapplication of the law, but rather the shortcoming in petitioner’s evidence.” *Id.* at 543.

On remand, the parties declined the opportunity to file additional materials. The Special Master again held that petitioner had failed to demonstrate that the vaccinations had caused her thyroid disease. *Shapiro III*, 2012 WL 273686. He found that petitioner had failed to meet, by a preponderance of the evidence, the proof requirements set forth in *Althen*, 418 F.3d at 1280. He found first, in this regard, that petitioner had failed to present a reliable medical theory causally connecting the vaccination and the injury, as required by *Althen*. *Shapiro III*, 2012 WL 273686, at \*5. Petitioner’s expert had proposed four separate possible theories, but each one, the Special Master determined, was not only lacking in scientific support, but contradicted by more persuasive evidence provided by defendant’s expert. *Id.* at \*5-8. The Special Master further found that petitioner had failed to show an appropriate temporal relationship between her first vaccination and the onset of her symptoms, as required by *Althen*. *Id.* at \*9. According to the Special Master, defendant’s expert credibly explained that thyroid disease progresses so slowly that developing it within the first three weeks after vaccination – as petitioner did – was “simply not plausible.” *Id.* at \*10. Finally, the Special Master held that, based upon her failure to present a reliable medical theory or an appropriate temporal relationship, petitioner could not show a logical sequence of cause and effect showing that the vaccination was the reason for the injury, the final requirement of *Althen*. *Id.* at \*11.

On February 9, 2012, petitioner filed a second motion for review, together with a motion seeking reconsideration of this court’s prior ruling on petitioner’s SLE claim. On March 8, 2012, respondent filed its opposition to petitioner’s motion for review; the court did not request, and respondent did not file a response to petitioner’s motion for reconsideration. Argument on these motions is deemed unnecessary.

## II. DISCUSSION

Under the Vaccine Act, this court may review a special master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). In that instance, the court may: “(A) uphold the findings of fact and conclusions of law . . . ; (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or; (C) remand the petition to the special master for further action in accordance with the court's direction.” *Id.* at § 300aa-12(e)(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an “arbitrary and capricious” standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec’y of Health and Human Servs.*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992); *see also Doyle ex rel. Doyle v. Sec’y of Health and Human Servs.*, 92 Fed. Cl. 1, 5 (2010).

Within this framework, petitioner makes several basic claims. First, she asserts that the Special Master incorrectly determined that her thyroid disease began prior to her vaccinations, arbitrarily and capriciously ignoring evidence that the thyroid disease began shortly following vaccination. She also argues that the Special Master held her medical theories of causation of her thyroid disease to an impermissibly high standard of proof. Petitioner also requests that this court reconsider its earlier ruling on SLE, arguing that the evidence on the record shows that her SLE began during the appropriate time period immediately following her vaccinations.

### A. Motion for Review – Hypothyroidism

Special Master Moran rejected petitioner's claim that she developed hypothyroidism in reaction to the hepatitis-B vaccine because he found that she had not provided a persuasive medical theory causally connecting the vaccine to her condition. In this regard, the Special Master found that petitioner's expert, Dr. Shoenfeld, had failed to demonstrate that any of the four theories of causation he offered – molecular mimicry, bystander activation through adjuvant, polyclonal activation, and interferon alpha – could account for the hepatitis-B vaccine causing petitioner's hypothyroidism. He also concluded that the onset of her thyroid symptoms occurred well before the medically appropriate time in which the vaccine could have been the cause.

Under what is commonly referred to as *Althen's* first prong, a vaccine claimant is obliged to show a “medical theory causally connecting the vaccination and the injury.” *Althen*, 418 F.3d at 1278. In *Simanski v. Sec’y of Health and Human Servs.*, 671 F.3d 1368, 1384 (Fed. Cir. 2012), the Federal Circuit recently described what this standard entails –

Although a finding of causation “must be supported by a sound and reliable medical or scientific explanation,” causation “can be found in vaccine cases . . . without detailed medical and scientific exposition on the biological mechanisms.” *Knudsen v. Sec’y of the Dep’t of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of the evidence that there is a

causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *Moberly* [*v. Sec'y of Health And Human Servs.*], 592 F.3d [1315], 1325 (Fed. Cir. 2010); *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009).

*See also* *Porter v. Sec'y of Health and Human Servs.*, 663 F.3d 1242, 1249-50 (Fed. Cir. 2011); *Lombardi v. Sec'y of Health and Human Servs.*, 656 F.3d 1343, 1351 (Fed. Cir. 2011). “[T]he purpose of the Vaccine Act’s preponderance standard,” the Federal Circuit has stated, “is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body,” even if the possible link between the vaccine and the injury is “hitherto unproven.” *Althen*, 418 F.3d at 1280; *see Porter*, 663 F.3d at 1261. Under the vaccine compensation system created by Congress, “close calls regarding causation are resolved in favor of injured claimants.” *Id.* (citing *Knudsen*, 35 F.3d at 549).

At the hearing, defendant’s expert, Dr. Ward, testified that he was unaware of any scientific or epidemiological evidence of a causal link between the hepatitis-B vaccine and thyroid disease. Petitioner’s expert, Dr. Shoenfeld, proffered four theories he claimed demonstrated that the hepatitis-B vaccine might cause autoimmune thyroid disease. On remand, the Special Master examined each of these theories in detail, weighing the scientific evidence presented by each side.

Dr. Shoenfeld’s first theory – and the one that he believed was the most plausible mechanism for the autoimmune reaction that led to petitioner’s injury – involved a biological mechanism known as “molecular mimicry.” As noted by the Special Master, “[t]his theory postulates that the molecular structure of the hepatitis B vaccine resembles the structure of thyroid tissue,” causing the body’s immune response to the vaccine to be “misdirected at its own tissue.” *Shapiro III*, 2012 WL 273686, at \*6. However, as defendant’s expert, Dr. Ward, pointed out, Dr. Shoenfeld’s own published work contradicts this theory, for it concludes that there is “no obvious similarity” between the hepatitis-B vaccine genome and “human proteins.” *Id.* (quoting Carlo Selmi et al., “Vaccines in the 21<sup>st</sup> century: the genetic response and the innocent bystander,” 4 *Autoimmunity Reviews* 79 (2005) at 2). As the Special Master noted, neither Dr. Shoenfeld, nor any other aspect of petitioner’s proof, addressed this earlier study. *Id.*

Dr. Shoenfeld’s next two theories involved “bystander activation” and “polyclonal activation,” respectively. The first of these theories suggests a reaction by the body to the aluminum salts found as an adjuvant in the hepatitis-B vaccine; the second focuses on the reaction to the vaccine experienced by individuals with a rare genetic background. In both instances, however, Dr. Shoenfeld directed his comments about these theories to SLE and not to petitioner’s autoimmune thyroid disease. And, even in this other context, the Special Master properly found that the testimony was “extremely cursory,” and contradicted by Dr. Ward’s testimony that there was no evidence supporting the application of these theories to the hepatitis-B vaccine. 2012 WL 273686, at \*7-8.

Dr. Shoenfeld’s fourth and final theory implicated “interferon alpha” – part of the immune system that prevents viruses from replicating. The Special Master noted that Dr.

Shoenfeld could produce no support for his theory. More importantly, he noted that Dr. Ward had convincingly observed that the hepatitis-B vaccine was incapable of inducing interferons because, unlike a virus, it “contains only a portion of the surface antigen” and thus “does not replicate.” *Id.* at \*7. The Special Master noted that Dr. Ward supported his opinion by citing three studies in which people who were infected with the hepatitis-C virus, a disease that elicits a strong interferon response, were safely administered the hepatitis-B vaccine. *Id.* & n.9 (citing the studies). The Special Master noted that while Dr. Ward had thus given a specific reason for questioning the reliability of Dr. Shoenfeld’s “interferon alpha” theory, petitioner had provided no reason to question the reliability of Dr. Ward’s testimony. *Id.* at \*7.

Based on his careful review, the Special Master concluded that petitioner had provided no indication that her theories accounted for her injury and no rebuttal to the countervailing evidence provided by respondent on this count. *Id.* at \*8. Contrary to petitioner’s claims, the Special Master did not apply a causation standard more strict than that authorized by law. *Cf. Porter*, 663 F.3d at 1253.<sup>5</sup> Rather, carefully examining each of these theories, the Special Master found each to be flawed and concluded that “Ms. Shapiro’s case falls short of the preponderance of the evidence standard.” 2012 WL 273686, at \*8. As has often been noted by the Federal Circuit, “‘reversible error will be extremely difficult to demonstrate’ where the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.’” *Porter*, 663 F.3d at 1253-54 (quoting *Hines v. Sec’y of Health and Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)); *see also Lombardi*, 656 F.3d at 1353. Such is the case here. Unlike his first opinion, the Special Master’s most recent opinion reveals a thorough and careful evaluation of all of the evidence, including records, tests, reports and medical literature, as well as the experts’ opinions. Weighing all this, the Special Master properly concluded that petitioner had not carried her burden of demonstrating “a medical theory causally connecting” the hepatitis-B vaccine to autoimmune thyroid disease. *Shapiro III*, 2012 WL 273686, at \*1. The court sees no reason to overturn these well-supported findings.

Putting aside the Special Master’s findings regarding causal link, it remains that petitioner still failed to meet the proof requirements of *Althen*’s third prong, under which she was obliged to show a “proximate temporal relationship between vaccination and injury.” *Althen*,

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<sup>5</sup> The Special Master’s approach was consistent with the Federal Circuit’s recent decision in *Simanski*, 671 F.3d at 1384. In that case, the special master dismissed the case prior to receiving any evidence from the respondent because plaintiff’s expert had failed to produce “a clearly articulated theory” of how the vaccines in question caused the petitioner’s illness, including “identification and proof of specific biological mechanisms.” *Id.* The court found this standard “too demanding,” holding that a petitioner need only present a “sound and reliable” medical theory and demonstrate by a “preponderance of the evidence that there is a causal relationship between the vaccine and the injury,” even if there is no “conclusive evidence in the medical literature” linking the vaccine to the injury. *Id.* In the case *sub judice*, the Special Master merely required that the theories be reliable and meet the preponderance of the evidence standard. He found each of Dr. Shoenfeld’s explanations lacking in this regard, based upon major gaps and flaws in those theories, and instead was persuaded by Dr. Ward’s contradicting testimony.



418 F.3d at 1278. Under this requirement, petitioner had to provide “preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *de Bazan v. Sec’y of Health and Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008); *see also Simanski*, 671 F.3d at 1384; *Pafford v. Sec’y of Health and Human Servs.*, 451 F.3d 1352, 1358 (Fed. Cir. 2006). Under this test, petitioner was first required to establish the timeframe for which it is medically acceptable to infer causation, that is, the timeframe in which symptoms would be expected to arise if the SLE was caused by the vaccination. Then, she was obliged to show that the onset of her SLE occurred during this causation period. *See de Bazan*, 539 F.3d at 1352 (stating, “we see no reason to distinguish between cases in which onset is too soon and cases in which onset is too late”); *Campbell v. Sec’y of Health and Human Servs.*, 97 Fed. Cl. 650, 671 (2011).

In this regard, the Special Master found, based upon considerable evidence that, “[t]he etiology of an autoimmune thyroid disease appears to be months or years.” *Shapiro III*, 2012 WL 273686, at \*9. And, he further found, based upon uncontradicted evidence, that “Ms. Shapiro’s manifestation of autoimmune thyroid disease occurred too quickly,” *i.e.*, within two to three weeks. *Id.*<sup>6</sup> Accordingly, on this basis alone, the court is compelled to sustain the Special Master’s finding that the hepatitis-B vaccine did not trigger petitioner’s injury.<sup>7</sup>

## **B. Motion for Reconsideration – SLE**

Although petitioner seeks reconsideration of this court’s prior ruling under RCFC Appendix B (Vaccine Rules), Rule 23, it would appear that any reconsideration of this court’s ruling sustaining the Special Master’s decision regarding petitioner’s SLE claim must arise under RCFC 59.<sup>8</sup> *See Hall v. Sec’y of Health and Human Servs.*, 93 Fed. Cl. 239, 251-52 (2010), *aff’d*, 640 F.3d 1351 (Fed. Cir.), *cert. denied*, 132 S. Ct. 815 (2011); *see also Patton v. Sec’y of Health & Human Servs.*, 25 F.3d 1021, 1028-29 (Fed. Cir. 1994); *Waller v. Sec’y of Health and Human Servs.*, 76 Fed. Cl. 321, 325 (2005).

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<sup>6</sup> Petitioner implies that it was her SLE, not her thyroid disease, that caused the symptoms that began shortly after her first vaccination. But, in other portions of her briefs, she admits to experiencing symptoms of hypothyroidism during this same period. For his part, Dr. Shoenfeld cited the constipation and palpitations that petitioner experienced shortly after her first vaccination as “very classical to . . . autoimmune thyroid disease.” He indicated further that petitioner’s constipation was not symptomatic of SLE. The record thus supports the Special Master’s finding that the onset of petitioner’s autoimmune thyroid disease does not arise at a time that can be explained as being a reaction to her first hepatitis-B vaccination.

<sup>7</sup> The Special Master gave additional reasons for this conclusion. Based upon its other conclusions, the court need not further examine that analysis here.

<sup>8</sup> Vaccine Rule 36 discusses motions for reconsideration filed “after the entry of judgment” and is seemingly inapplicable here. *See also Vessels v. Sec’y of Health & Human Servs.*, 65 Fed. Cl. 563 (2005).

To prevail on a motion for reconsideration under RCFC 59, the movant must identify a “manifest error of law, or mistake of fact.” *Fru-Con Constr. Corp. v. United States*, 44 Fed. Cl. 298, 300 (1999) (quoting *Bishop v. United States*, 26 Cl. Ct. 281, 286 (1992)), *aff’d*, 250 F.3d 762 (Fed. Cir. 2000); *see also Alli v. United States*, 86 Fed. Cl. 33, 34 (2009); *Six v. United States*, 80 Fed. Cl. 694, 697 (2008). Specifically, the moving party must show: (i) an intervening change in controlling law; (ii) the availability of previously unavailable evidence; or (iii) the necessity of granting the motion to prevent manifest injustice. *Petro-Hunt, L.L.C. v. United States*, 2012 WL 1957929, at \*1 (Fed. Cl. May 30, 2012); *Stovall v. United States*, 86 Fed. Cl. 770, 771 (2009). The court has considerable discretion in ruling on a motion for reconsideration. *See Yuba Natural Res., Inc. v. United States*, 904 F.2d 1577, 1583 (Fed. Cir. 1990); *see also Stovall*, 86 Fed. Cl. at 771; *Banks v. United States*, 84 Fed. Cl. 288, 291 (2008). Nonetheless, granting such relief requires “a showing of extraordinary circumstances.” *Caldwell v. United States*, 391 F.3d 1226, 1235 (Fed. Cir. 2004) (citation omitted), *cert. denied*, 546 U.S. 826 (2005); *see also Stovall*, 86 Fed. Cl. at 772; *Alli*, 86 Fed. Cl. at 34.

Petitioner does not claim that there has been an intervening change in the law, nor does she contend that there is new evidence that was unavailable at the time of the court’s prior decision. She must, therefore, demonstrate that the denial of her motion for reconsideration would result in a manifest injustice. *See Hall*, 93 Fed. Cl. at 251.

In its original decision, the court held that petitioner had failed to establish that the development of her SLE occurred within the medically appropriate interval. As this court explained, “petitioner failed to demonstrate that she had SLE symptoms during the accepted temporal causation period; rather, it appears that her SLE symptoms manifested themselves months after she received her second vaccination.” *Shapiro II*, 101 Fed. Cl. at 543. Commenting on petitioner’s disagreement with this finding, the court adumbrated –

the denial of her SLE claim was based on the Special Master’s weighing of the evidence. Laid bare, petitioner’s arguments reflect little more than mere disagreement with the finding that petitioner failed to establish a proximate temporal relationship between the vaccination and the onset of the SLE. “Such naked claims,” this court has stated, “by all appearances unsupported by anything in the record, fall far short of meeting the heavy burden of demonstrating that these findings were the product of an irrational process and hence arbitrary and capricious.” *Doyle*, 92 Fed. Cl. at 7 (quoting *JWK Int’l Corp. v. United States*, 52 Fed. Cl. 650, 660 (2002), *aff’d*, 56 Fed. Appx. 474 (Fed. Cir. 2003)).

*Shapiro II*, 101 Fed. Cl. at 543. The court went on to reject petitioner’s claim that the court should overrule the Special Master’s findings based on the contrary – albeit unsupported – conclusion of its expert, Dr. Shoenfeld, observing that “proof of causation entails more than having a well-qualified expert proclaim that the vaccination caused a disease.” *Shapiro II*, 101 Fed. Cl. at 543 n.15 (quoting *Doyle*, 92 Fed. Cl. at 8).

In *Shapiro II*, petitioner offered very little to rebut the Special Master’s finding that she had failed to demonstrate that her SLE symptoms arose during the accepted temporal causal

period. *Shapiro II*, 101 Fed. Cl. at 543. And, here, petitioner offers even less in seeking reconsideration of this court's decision upholding the Special Master's finding. Indeed, petitioner raises nothing new, but merely reargues evidence and expert opinions that the Special Master and, in turn, this court have already rejected. For example, petitioner contends that the Special Master arbitrarily set the date of onset as the first date on which SLE was mentioned in her medical records. But, petitioner overlooks the fact that the primary deficiency in her proof on this count was the absence of any evidence indicating that her SLE symptoms began during the appropriate time period following her vaccinations. To the extent that petitioner argues otherwise, her factual allegations are no more compelling this – the third – time around. No manifest injustice has been demonstrated and reconsideration, therefore, is not in order.

### **III. CONCLUSION**

This court need go no further. For the foregoing reasons, the court **DENIES** petitioner's motion for review, as well as her motion for reconsideration.<sup>9</sup>

**IT IS SO ORDERED.**

s/ Francis M. Allegra  
Francis M. Allegra  
Judge

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<sup>9</sup> This opinion shall be unsealed, as issued, after July 5, 2012, unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to that date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons therefor.