United States Court of Appeals for the Federal Circuit

CHERYL LOMBARDI,
Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

2011-5004

Appeal from the United States Court of Federal Claims in Case No. 99-VV-523, Judge Marion Blank Horn.

Decided: September 6, 2011

CLIFFORD J. SHOEMAKER, Shoemaker & Associates, of Vienna, Virginia, argued for the petitioner-appellant.

HEATHER L. PEARLMAN, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for the respondent-appellee. With her on the brief were TONY WEST, Assistant Attorney General, TIMOTHY P. GARREN, Director, MARK W. ROGERS, Deputy Director, and CATHARINE E. REEVES, Assistant Director.

Before RADER, *Chief Judge*, and LOURIE and O'MALLEY, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE.
Concurring opinion filed by *Circuit Judge* O'MALLEY.

LOURIE, *Circuit Judge*.

Cheryl Lombardi appeals from the decision of the United States Court of Federal Claims ("Claims Court") affirming the decision of a special master denying compensation under the Vaccine Act for injuries that she alleged were a result of receiving hepatitis B vaccinations. *Doe v. Sec'y of Dept. of Health & Human Servs.*, 94 Fed. Cl. 597 (2010) ("*Claims Court Op.*"). Because we agree with the Claims Court that the special master did not err in concluding that Lombardi failed to prove by a preponderance of the evidence that she suffered the alleged injuries, we affirm.

BACKGROUND

A. Facts of the Case

The facts in this case are mostly undisputed. Lombardi was born on October 17, 1946. She received the first dose of the hepatitis B vaccine on April 1, 1997, and the second dose on May 6, 1997. She suffered no immediate adverse reactions to those first two doses. On October 28, 1997, she received a third dose of the vaccine. Then, on November 9, 1997, Lombardi visited a hospital emergency room, complaining of right flank pain radiating into her right chest. Various tests were performed, but the evaluation failed to find a cause of her symptoms. She was discharged the same day with a diagnosis of atypical chest pain. Lombardi returned to the emergency room on November 14, 1997, once again complaining of right flank

pain. The various tests that were performed on her during that visit also failed to detect any identifiable problems.

On January 15, 1998, Lombardi sought treatment from an internal medicine specialist, Dr. Michael Conaway. Records from that visit document Lombardi's complaints of ongoing pain on her right side, as well as weakness and fatigue. Lombardi also informed Dr. Conaway that she had experienced a weight gain of 40 pounds in the past five years. Dr. Conaway reviewed the results of tests on blood drawn on January 13, 1998, which indicated that petitioner had a positive antinuclear antibody ("ANA") rate. Dr. Conaway's notes indicate that Lombardi had a chest X-ray that showed some pleural thickening and that he ordered additional tests to determine whether petitioner had systemic lupus erythematosus ("SLE"). Those notes also indicate that Lombardi had consulted Dr. Cordasco and was undergoing a work-up for possible SLE.

In February 1998, Dr. Teresa George, a rheumatologist, evaluated Lombardi for possible SLE, but found nothing based on that examination. Instead, the doctor noted that Lombardi had a history of joint pain which was not associated with swelling. Dr. George wrote that Lombardi denied having any skin rashes, hair loss, photosensitivity, or changes in memory or concentration. Dr. George also noted a higher ANA rate, but found all other laboratory tests, including other serologies for diagnosing SLE, were normal. She suspected that Lombardi "probably had a positive ANA in the past," and concluded that her right chest pain was of "unclear etiology" and that there was not "enough evidence for systemic lupus erythematosis [sic] or another autoimmune process at this time."

In February and March 1998, Lombardi returned to Dr. Conaway three times with complaints of right-sided pain, nausea, and fatigue. After conducting a thorough workup, Dr. Conaway wrote that he was "really at a loss to explain both her pain and her fatigue at this point." After Lombardi's third visit, Dr. Conaway referred her to the Cleveland Clinic to obtain a more comprehensive diagnostic evaluation.

On March 16, 1998, Lombardi saw Dr. John Campbell, a preventative medicine specialist at the Cleveland Clinic. Dr. Campbell ordered blood tests, which revealed that Lombardi had a vitamin B12 deficiency and an elevated level of methylmalonic acid. He directed her to have additional tests performed and to see a neurologist. A radiology report from that time indicates that Lombardi had decreased bone density, consistent with osteopenia of her lumbar spine, and osteoporosis in her left hip. On one of the physical evaluation forms entitled "impressions," Dr. Campbell's notes state "post hepatitis B—fatigue," followed by an illegible word. On April 9, 1998, Lombardi was examined by Dr. Patrick Sweeney, a neurologist at the Cleveland Clinic, and Dr. Ian Lavery in the colorectal surgery department. Dr. Lavery did not diagnose any problems and Dr. Sweeney was doubtful that Lombardi suffered from any neurologic problem, stating in his notes that he "doubt[ed] neuro disease." Following her return from the other Cleveland Clinic physicians, Dr. Campbell summarized his findings, based on their evaluations, as "post vaccine syndrome." Dr. Campbell's recommendation to Lombardi was that she take B12 and follow up with her local physician.

On April 23, 1998, Dr. Conaway assessed Lombardi with chronic fatigue, expressing uncertainty as to whether the mild vitamin B12 deficiency could explain her symptoms. Lombardi reported that she could walk

only for about ten minutes before becoming exhausted. Dr. Conaway also noted that Lombardi had "chronic right lateral rib cage pain," but was unable to determine a cause of the pain. At the visit, Dr. Conaway referred Lombardi to Dr. Elizabeth Hurst for a psychological evaluation to investigate whether underlying depression or trauma could account for her symptoms. There is no record of Lombardi's visit to Dr. Hurst.

On May 1, 1998, Lombardi returned to Dr. Conaway explaining that a friend had told her about a news report suggesting that hepatitis B vaccine could lead to chronic fatigue by causing rheumatologic problems. In his notes from that visit, Dr. Conaway was doubtful of that diagnosis, noting that the "fact that I have seen no objective signs of a rheumatologic condition and her [erythrocyte sedimentation] rate has always been normal combined with the fact that she has not responded in the past to [non-steroidal anti-inflammatory drugs] and/or steroids tend to push me away from that diagnosis." Dr. Conaway did however indicate that he was "unsure what to make of her positive ANA."

In July 1998, Lombardi saw Dr. Andrew Campbell, a specialist with experience evaluating chronic fatigue syndrome due to the hepatitis B vaccine. Dr. Campbell assessed her as having fatigue, chest pain, and polyneuropathy. On another visit a few weeks later, Dr. Campbell again diagnosed Lombardi as having fatigue and polyneuropathy. He added the diagnosis of an adverse reaction to a vaccine, and recommended a reassessment in 90 days. Dr. Campbell's notes from another visit three weeks later stated that the decline in Lombardi's health was a direct result of her hepatitis B vaccination. Later, in October 1998, Dr. Campbell indicated that she also suffered from high cholesterol and prescribed vitamins, including a vitamin B complex.

On October 6, 1998, Lombardi visited Dr. Albert Beraducci of Neurologic Associates, Inc., but there is no diagnosis from that visit in the record. On October 30, 1998, she saw Dr. Joseph Plouffe, an infectious disease specialist, who also found that specific antibodies to test for SLE were negative. Dr. Plouffe concluded that petitioner had a "[p]ossible immunologic process of questionable etiology Hep B vaccine certainly possible." Throughout 1999, Lombardi continued to see Dr. Andrew Campbell with little change in her condition. On September 24, 1999, petitioner again had a positive ANA test. In late 1999, following another positive ANA test, Dr. Campbell began intravenous immunoglobin treatment for chronic inflammatory demyelinating polyneuropathy and Lombardi remained on the treatment through at least May 2000.

In August and September 1999, Lombardi visited Dr. Sandra Stewart–Pinkham, a pediatrician who assessed that her problems were "best explained by an adverse reaction to hepatitis B vaccine which contains 25 mcg of mercury in each injection." Dr. Stewart–Pinkham noted that Lombardi's problems "are identical to individuals with chronic fatigue immune dysfunction, a disease of unknown etiology." Lombardi was evaluated by a dermatologist, Dr. Adam Hessel, in September 2001 for a recurrent episodic rash. A skin biopsy was performed on March 7, 2002, after which petitioner was diagnosed with Wells Syndrome. Dr. Hessel indicated that Wells Syndrome "could be seen in association with a vaccination reaction" but that the "relationship is uncertain." Dr. Hessel later concluded that the rash was likely caused by a reaction to toxic black mold found in her home.

On June 18, 2004, a CT scan of Lombardi's abdomen indicated a tiny, unobtrusive stone in the upper portion of the right kidney and an even smaller stone possibly in the

lower portion of the right kidney. The study was otherwise normal. Urologist Dr. Bruce E. Woodworth stated that based on the CT scan results, "one wonders if the patient's episodes of right flank pain may be due to passage of tiny calculi." A radiographic examination of Lombardi's cervical spine taken on October 28, 2004, showed multilevel degenerative disk disease with spondylosis and compression of the spinal cord at levels C5–6 to the left and C6–7 to the right, associated with disc protrusions and foraminal stenoses. In a November 10, 2004, Progress Note, Dr. Conaway assessed petitioner with "1. Cervical disk degeneration [and] cervical spinal stenosis" and "2. Chronic Fatigue Syndrome." He referred her to a chiropractor and an anesthesiologist for a steroid injection. During the pendency of this litigation, Lombardi was also being treated by Dr. Kevin Schlessel, a rheumatologist.

Other pertinent details from Lombardi's medical history include the fact that she became a vegetarian at the age of 25, underwent a hysterectomy at the age of 31, and had her appendix removed in her early 30s. At the age of 37, Lombardi had problems with her gallbladder and subsequently underwent surgery for its removal. In August 1990, her only child died under tragic and extraordinary circumstances. At the time of vaccination, Lombardi was employed at Abbott Laboratories, where she packaged medical devices and worked with a chemical called cyclohexane. Prior to working at Abbott, Lombardi was employed at Ross Laboratories, where her duties involved handling boxes contaminated with bodily fluids.

B. Claims Court Proceedings

On July 28, 1999, Lombardi filed a petition under 42 U.S.C. §§ 300aa-1, et seq. (2006) ("the Vaccine Act") seeking compensation for certain injuries that she

claimed were a result of her hepatitis B vaccinations. The petition did not identify any injuries, but claimed that she had sought frequent medical treatment following the vaccination. Subsequently, Lombardi focused her case and offered expert opinions in support of claims that she suffered from three different conditions that are not listed on the Vaccine Injury Table—transverse myelitis, chronic fatigue syndrome, and SLE.

The case was assigned to a special master of the Claims Court who conducted three evidentiary hearings. Because Lombardi claimed off-Table injuries, she was required to prove causation in fact. *See* § 300aa-11(c)(1)(C)(ii). Both parties retained medical experts, who submitted reports and testified at the hearings regarding Lombardi's condition and whether the hepatitis B vaccine caused her injuries. The government's experts included Dr. Thomas Leist, a neurologist, and Dr. Lawrence Kagen, a rheumatologist. Lombardi also retained two experts: Dr. Carlo Tornatore, a neurologist, and Dr. Yehuda Shoenfeld, an immunologist and rheumatologist. On December 1, 2006, at Dr. Tornatore's request, an MRI of Lombardi's thoracic spine was performed. The condition stated in the resulting radiology report was "mild atrophy of thoracic cord at mid thoracic levels: without neurally compressive lesion or intrinsic focal cord lesion depicted."

At the first hearing on November 1–2, 2007, Dr. Tornatore testified that Lombardi's MRI indicated atrophy, which in his opinion was caused by transverse myelitis that he concluded resulted from the hepatitis B vaccine. Dr. Leist offered his opinion that Lombardi suffered from (1) a vitamin B12 deficiency; (2) an evolving, mixed collagen vascular disorder; and (3) osteopenia, with degenerative changes in her cervical spine. Dr. Leist rejected Dr. Tornatore's hypothesis that Lombardi suffered from

transverse myelitis as a result of the series of hepatitis B vaccinations.

At the second hearing, on April 9, 2008, Dr. Shoenfeld, Lombardi's expert, testified that Lombardi suffered from chronic fatigue syndrome, which was a "direct result" of the hepatitis B vaccine. Although not stated in his expert report, Dr. Shoenfeld opined for the first time at that hearing that Lombardi's condition met the diagnostic criteria for SLE, which he believed was also caused by the hepatitis B vaccinations. Dr. Kagen, the government's expert, offered multiple possible diagnoses for Lombardi's condition, but did not comment as to whether she suffered from chronic fatigue syndrome. Dr. Kagen's list of diagnoses included (1) a mixed connective tissue disease with rheumatoid arthritis overlap, (2) osteoarthritis with spinal cord and nerve root compression, (3) a nutritional deficit due to a lack of vitamin B12 in her diet, (4) an allergic reaction to mold, and (5) depression.

At the third hearing, on November 25, 2008, Dr. Kagen testified that Lombardi did not meet the diagnosis for SLE under the criteria set out by the American College of Rheumatology ("ACR"). Dr. Shoenfeld reiterated his diagnosis of SLE.

On January 29, 2010, the special master published an opinion denying Lombardi's entitlement under the Vaccine Act. *Doe 60 v. Sec'y of Health & Human Servs.*, No. 99-VV-523, 2010 WL 1506010 (Fed. Cl. Mar. 26, 2010) ("*Special Master Op.*"). The special master conducted a thorough analysis of all the tests performed on Lombardi, and the opinions of the treating physicians as well as the conflicting opinions of the testifying experts. *See id.* at *12–33. The special master concluded that petitioner was not entitled to compensation because she had "not estab-

lished that she suffers from any of the three conditions that provide the basis for her experts' opinions." *Id.* at *1. The special master stated that under our holding in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), when a petitioner claims compensation for an injury not listed on the Vaccine Injury table, the petitioner must establish three elements, the second being a logical sequence of cause and effect showing that the vaccination was the reason for the injury. However, because the special master found that Lombardi had failed to establish that she suffered from any specific injury, he found no need to determine whether the claimed conditions were caused by vaccination under the second prong of *Althen*. *Special Master Op.* at *12.

With regard to transverse myelitis, the special master concluded that Lombardi's clinical presentation between November 1997 and April 1998 was not consistent with the signs and symptoms of transverse myelitis. *Id.* at *17. He noted that her treating doctors, including her treating neurologist, had never diagnosed her with transverse myelitis and that the 2006 MRI, the only imaging study done on Lombardi, did not counter the conclusions reached by her treating doctors. *Id.*

On Lombardi's second claim, the special master acknowledged that Lombardi had experienced some of the symptoms attributable to chronic fatigue syndrome, but also found a number of alternative causes for her fatigue, including vitamin B12 and thiamine deficiency. *Id.* at *24. Further, he noted that most of Lombardi's treating doctors did not diagnose her with chronic fatigue syndrome, a diagnosis that requires chronic fatigue plus ancillary factors and the exclusion of other causes of the fatigue. *Id.*

With regard to Lombardi's SLE claim, the special master employed criteria issued by the ACR, requiring that at least four of the eleven symptoms be met in order for a diagnosis of SLE to be made. *Id.* at *25. The special master concluded that Lombardi met only three. *Id.* at *29. Moreover, he noted that from 1997 to 2007, none of Lombardi's numerous treating doctors had ever diagnosed her as suffering from SLE, some of them even having specifically investigated Lombardi for SLE. *Id.* In conclusion, the special master reasoned that while the answer to what Lombardi suffered from was elusive, it was not the government's burden to provide that answer. *Id.* at *31. The special master thus denied Lombardi's petition for compensation under the Vaccine Act.

Lombardi sought review of the special master's decision in the Claims Court. The Claims Court affirmed the special master's decision, concluding that the special master properly considered the entire record. *Claims Court Op.*, 94 Fed. Cl. at 624. The Claims Court concluded that the special master was not arbitrary or capricious in his decision and had laid out a detailed assessment of whether petitioner had proven each diagnosis—transverse myelitis, chronic fatigue syndrome, and SLE—for which she alleged entitlement to compensation. *Id.* The Claims Court also concluded that the special master had considered, and properly rejected, whether Lombardi could recover under a medical theory of a non-labeled, medical syndrome or symptomatology giving rise to a non-identified autoimmune disease. *Id.* The Claims Court noted that there was no agreement among Lombardi's expert witnesses, her treating physicians, or in the underlying medical records, as to any injury, symptomatology, or medical diagnosis from which Lombardi suffered following her hepatitis B vaccinations. *Id.* The court therefore held that such a record of divergent diag-

noses and symptoms could not support an analysis under *Althen*. *Id.*

Lombardi appeals the decision of the Court of Federal Claims. We have jurisdiction pursuant to 42 U.S.C. § 300aa-12(f).

DISCUSSION

We review an appeal from the Claims Court in a Vaccine Act case *de novo*, applying the same standard of review as the Claims Court applied to its review of the special master's decision. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009). We owe no special deference to the Claims Court or the special master on questions of law. *Id.* Whether the special master applied the appropriate standard of causation is a legal determination reviewed by this Court *de novo* under the "not in accordance with law" standard. *See Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870–73 (Fed. Cir. 1992). We uphold the special master's findings of fact unless they are arbitrary or capricious. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006). "Thus, although we are reviewing as a matter of law the decision of the Claims Court under a non-deferential standard, we are in effect reviewing the decision of the special master under the deferential arbitrary and capricious standard on factual issues." *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1369 (Fed. Cir. 2000).

A petitioner seeking compensation under the Vaccine Act must prove by a preponderance of the evidence that the injury or death at issue was caused by a vaccine. 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1). If the claimed injury is not listed in the Vaccine Injury Table ("off-Table injury"), the petitioner may seek compensation by proving causation in fact. *Moberly v. Sec'y of Health & Human Servs.*,

592 F.3d 1315, 1321 (Fed. Cir. 2010); 42 U.S.C. § 300aa-11(c)(1)(C)(ii). When a petitioner has suffered an off-Table injury, we have established the following test for showing causation in fact under the Vaccine Act:

> [The petitioner's] burden is to show by preponderant evidence that the vaccination brought about her 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, 418 F.3d at 1278. "[T]he function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine 'based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury.'" *Andreu*, 569 F.3d at 1382 (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)).

Lombardi argues that she has demonstrated by a preponderance of the evidence that hepatitis B vaccination caused her injuries. According to Lombardi, she was denied compensation merely because her medical condition is complex and she suffers from more than one injury. Lombardi contends that under the standard employed by the special master and the Claims Court, she would have to provide direct evidence of a single unwavering specific diagnosis without the possibility of any other diagnosis in order to succeed on her claim. She contends that the special master and the Claims Court erred by failing to analyze her condition under the *Althen* test merely because her treating doctors and experts suggested different diagnoses. Lombardi argues that she proffered sufficient

evidence that she suffered from each of the three conditions, transverse myelitis, chronic fatigue syndrome, and SLE, thus requiring the special master to conduct a causation analysis under *Althen*. Instead, Lombardi continues, the special master improperly shifted to her the government's burden of proving that her condition was unrelated to the vaccination.

The government responds that the special master and Claims Court applied the correct legal standard in reviewing Lombardi's case, and properly concluded that she had failed to establish by a preponderance of the evidence that she suffers from any of the three claimed diseases. According to the government, the special master did not impose the government's burden on her, or raise her burden of proof to require absolute certainty as to each of the diagnoses. Instead, the government contends, he provided a sound rationale for his conclusions, detailing why appellant's experts failed to offer reliable evidence to establish any prima facie case, and these factual findings are entitled to significant deference under this court's precedent. The government further argues that there was no need to evaluate Lombardi's claim for causation under *Althen* because she failed to show that she actually suffers from the specific conditions that she alleges. According to the government, it would be illogical for the special master to assess whether or not the hepatitis B vaccine caused those injuries when she has failed to prove that she suffers from them.

We agree with the government that the special master properly denied Lombardi's claim for compensation under the Vaccine Act. Lombardi's primary argument is that she is entitled to recover once she proves by a preponderance of the evidence that the vaccine caused her injury, and thus the special master was required to analyze causation. Instead of making that determination,

Lombardi continues, the special master and the Claims Court were focused on deciding if she even suffered from one of the three claimed conditions, thus requiring the petitioner to prove a specific diagnosis. That, according to Lombardi, imposed on her an improper burden of proving a diagnosis with scientific certainty even before she could prove causation under *Althen*. Lombardi's arguments, however, are unpersuasive in view of our recent precedent.

In *Broekelschen v. Secretary of Health & Human Services*, 618 F.3d 1339 (Fed. Cir. 2010), we addressed the same issue as that presented here. Dr. Broekelschen, the petitioner in that case, suffered from symptoms that were consistent with two different conditions—a vascular condition and an inflammatory condition—which differ significantly in their pathology. *Id.* at 1346. In ruling on his petition for entitlement under the Vaccine Act, the special master decided first to determine which injury Dr. Broekelschen suffered from, and then proceeded to determine whether the vaccinations caused that injury. *Id.* at 1344. Dr. Broekelschen had claimed and presented causation evidence on only one of those two conditions. Because the special master made a factual determination that the condition that Dr. Broekelschen actually suffered from was not the one for which he had claimed or presented causation evidence, he denied the petition. *Id.* As in this case, Dr. Broekelschen argued to us that the special master erred by failing first to determine whether Dr. Broekelschen had established a prima facie case that the vaccine caused the condition that the petitioner had alleged before determining that he actually suffered from that illness. *Id.* at 1345. We rejected that argument, explaining that the question of causation turned on which injury the petitioner suffered. *Id.* at 1346. We determined that if the existence and nature of the injury itself

is in dispute, it is the special master's duty to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test to determine causation of that injury. *Id.* That, we held, is mandated by the Vaccine Act, which creates a cause of action for persons suffering a "vaccine-related injury," 42 U.S.C. § 300aa-11(a), "*i.e.*, illness, disability, injury or condition, [that] has to be more than just a symptom or manifestation of an unknown injury," *Broekelschen*, 618 F.3d at 1349. Thus, under *Broekelschen*, identification of a petitioner's injury is a prerequisite to an *Althen* analysis of causation.

Lombardi's case, although unusual in that the identification of the injury and its nature is in dispute, is similar to *Broekelschen*. As the special master noted, Lombardi's case is complicated by the fact that she alleged that she suffers from three different medical conditions. It is further complicated by the fact that there was little agreement as to her symptoms or the diagnosis of her condition among her treating physicians or among the experts. *Special Master Op.* at *12. The special master pointed out that even the two experts that Lombardi retained specifically for this litigation differ in their opinions as to her "injury"—one of them diagnosed transverse myelitis, and the other offered two alternatives, chronic fatigue syndrome or SLE. *Id.* As the special master correctly observed, Lombardi "has not argued that the three conditions are so similar that doctors consider them to be conditions along a spectrum of diseases." *Id.* at *7 n.7. In contrast, the government's experts refuted each of those diagnoses and proposed five other possible conditions that Lombardi may have suffered from. In the face of such extreme disagreement among well-qualified medical experts, each of whom had evaluated the petitioner, it was appropriate for the special master to first

determine what injury, if any, was supported by the evidence presented in the record before applying the *Althen* test to determine causation. *Broekelschen*, 618 F.3d at 1346. In the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached.

Lombardi argues that by finding that she had failed to prove the existence of any of her injuries, and therefore declining to conduct an *Althen* analysis on any of her alleged injuries, the special master penalized her for alleging that she suffered from more than one injury. Lombardi misstates the special master's reasoning. The special master did not require Lombardi to narrow the number of alleged injuries to one. But the statute places the burden on the petitioner to make a showing of at least one defined and recognized injury. Here, the special master merely found that Lombardi had failed to meet her burden to show by a preponderance of the evidence that she suffered from any medically recognized "injury," not merely a symptom or manifestation of an unknown injury. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) (requiring that an off-Table injury petitioner must allege that he "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a Vaccine referred to in subparagraph (a)"). We therefore conclude that the special master imposed the proper burden on Lombardi.

Next, we review the special master's findings on each of Lombardi's claims. In reaching his conclusions, the special master thoroughly evaluated Lombardi's medical records as well as the medical opinions of several treating physicians and experts. We afford these findings of fact substantial deference. *Hines v. Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991) ("If the special master has considered the relevant evidence of record,

drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate."). We address each in turn.

A. Transverse Myelitis

Lombardi argues that Dr. Tornatore's testimony concerning his diagnosis of transverse myelitis after reviewing Lombardi's MRI, combined with the medical literature that he submitted to support his diagnosis, should have sufficed to demonstrate by a preponderance of the evidence that she had transverse myelitis. The special master, however, articulated several reasons for rejecting that diagnosis. First, the special master properly recognized the special value that we have placed on the opinions of treating physicians. *Special Master Op.* at *13 (citing *Capizzano*, 440 F.3d at 1326). The special master noted that the neurologist and rheumatologist treating Lombardi shortly after the vaccines were administered, namely, Dr. Sweeney, who conducted a complete neurological exam, and Dr. George, who performed a comprehensive evaluation, did not diagnose transverse myelitis. *Id.* at *14 (noting also that the "idea that petitioner suffers from transverse myelitis originated in this litigation"). The special master found that even Dr. Tornatore did not arrive at that diagnosis after reviewing medical records. Instead, Dr. Tornatore suggested that Lombardi undergo an MRI of her spine, reasoning that "if the MRI reveals a demyelinating lesion of the thoracic spine, . . . the etiology of her flank pain and its association with the hepatitis B vaccination would be clarified." *Id.* The MRI, however, failed to reveal a lesion, and showed only "mild atrophy of the thoracic cord." Yet, Dr. Tornatore found that result sufficient to diagnose transverse myelitis and further to connect it to Lombardi's symptoms nine years earlier. *Id.* at *15. It was not arbitrary or capricious for the special master to have rejected that expert testimony.

See Moberly, 592 F.3d at 1324. Moreover, the special master explained that Lombardi seems to have had none of the typical problems associated with transverse myelitis, such as numbness, weakness, sensory abnormalities, and problems with the bowel and bladder. *Special Master Op.* at *16. The special master's finding that many of Lombardi's complaints did not match the symptoms of transverse myelitis was not arbitrary or capricious. We thus affirm the special master's conclusion that Lombardi failed to establish that she suffered from transverse myelitis.

B. Chronic Fatigue Syndrome

Lombardi argues that the special master improperly rejected evidence, including medical records, showing that her treating physicians, Drs. Campbell and Stewart-Pinkham, diagnosed her with post-hepatitis B fatigue, and testimony from her expert, Dr. Shoenfeld, that she met at least four of the eight diagnostic criteria for chronic fatigue syndrome. We disagree. The special master explained that chronic fatigue syndrome is a diagnosis of exclusion, and should be made only after other chronically fatiguing conditions have been ruled out. *Id.* at *18 (citing the *Journal of Clinical Investigation*). Dr. Kagen testified that there were at least two alternative explanations for Lombardi's fatigue—vitamin B12 deficiency and osteoarthritis—that precluded the diagnosis of chronic fatigue syndrome. *Id.* at *19. There is also support in Lombardi's extensive medical records for a finding that she may have suffered from both of those conditions. Moreover, the special master found support in the cited medical literature that those two conditions could also explain some of her symptoms such as fatigue as well as joint and muscle pain.

In addition, the special master meticulously reviewed Lombardi's medical records to determine if any of her treating physicians had actually diagnosed her with chronic fatigue syndrome. He paid special attention to any "fatigue" reference in Lombardi's treating physician's statements, but concluded that they did not amount to preponderant evidence of chronic fatigue syndrome. *Id.* at *23–24. In doing so, he explained in detail his reasoning for rejecting each of the references as an actual diagnosis of that medical condition. *Id.*

The special master's decision on Lombardi's claim for chronic fatigue syndrome required reconciling conflicting testimony from opposing experts. He found the opinions of Dr. Leist and Dr. Kagen to be persuasive, but not Dr. Shoenfeld's. *Id.* at *20. We conclude that the special master reasonably weighed the evidence before him and that his decision on Lombardi's claim of chronic fatigue syndrome was well within the discretion granted to special masters under the vaccine program. *See Andreu*, 569 F.3d at 1379; *see also Munn*, 970 F.2d at 871 (We do not "reweigh the factual evidence, or . . . assess whether the special master correctly evaluated the evidence . . . or the credibility of the witnesses.").

C. SLE

Lombardi argues that the special master imposed an improper burden by employing the criteria developed by the American College of Rheumatologists for a diagnosis of SLE and requiring her to prove that she met at least four of the eleven criteria before such a diagnosis can be made. Lombardi contends that that requirement reflects a diagnosis of SLE with 96 percent certainty, and her burden under the Vaccine Act cannot be that high. Even so, Lombardi argues, Dr. Shoenfeld extensively detailed the presence of more than four of the required criteria; yet

the special master improperly discredited that opinion and arbitrarily denied Lombardi's claim.

We agree with the government that the special master's decision here was reasonable. First, we find no error in the special master's decision to analyze Lombardi's claim under the ACR's criteria. Those criteria are generally accepted in the medical community for diagnosing SLE, and Lombardi's own expert referenced them in analyzing her condition. The special master properly decided that her burden of showing that she suffers from SLE would have been satisfied if Lombardi could have demonstrated that she met the ACR's criteria for a diagnosis of SLE. *See Moberly*, 592 F.3d at 1322 (A petitioner needs to "provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case.").

The special master noted that the SLE claim was raised for the first time more than eight years after Lombardi's initial petition was filed. *Special Master Op.* at *24. Following her hepatitis B vaccinations, Lombardi's treating physicians actively investigated whether she suffered from SLE, but in the ten years that ensued, no doctor ever diagnosed her with that disease. On the contrary, two of her treating physicians affirmatively ruled out that diagnosis. *Id.* at *29. Yet, at a late stage of this litigation, Lombardi's expert Dr. Shoenfeld diagnosed her with SLE, contending that she met at least five of the ACR's criteria. The special master independently evaluated whether Lombardi met each of the eleven criteria. *Id.* at *25-29. The special master rejected Dr. Shoenfeld's characterization of Lombardi's upper lip rash as a malar rash, one of the eleven criteria. *Id.* at *25. Likewise, the special master rejected Dr. Shoenfeld's conclusion that Lombardi's joint pain, or arthralgia, demonstrated that she had arthritis, another ACR criterion. *Id.* at *27. He also rejected Dr. Shoenfeld's testi-

mony that Lombardi suffered from a neurologic disorder even though she did not experience any seizures or psychosis. *Id.* at *28. In each of those determinations, the special master relied upon the definitions as provided by the ACR. We find that decision to be rational and conclude that the special master's decision was legally supported in ruling that, at best, Lombardi fulfilled only three of the eleven criteria for a diagnosis of SLE, thereby not satisfying the diagnostic requirement for SLE.

Lombardi relies heavily on the opinion of her treating rheumatologist, Dr. Schlessel, who submitted a letter to the special master and who, Lombardi contends, is now treating her for SLE. Dr. Schlessel's short letter, however, appears to be written for the purpose of this litigation and his statement on Lombardi's condition is conclusory: "Please be advised that [Lombardi] has a number of complaints. Her laboratory tests will be consistent with a diagnosis of systemic lupus erythematosus." No "laboratory tests" were ever provided to the special master and there is no evidence in the record that they even exist. Moreover, Dr. Schlessel's statement appears to predict what Lombardi's test will reveal, rather than state an actual diagnosis of SLE. We do not fault the special master for rejecting such unreliable evidence. *Cf. Moberly*, 592 F.3d at 1324 ("[T]he special master is entitled to require some indicia of reliability to support the assertion of the expert witness."). We conclude that the special master's finding that Lombardi had not shown by a preponderance of the evidence that she suffered from SLE was not arbitrary or capricious.

Lastly, we reject Lombardi's argument that, given his record, the special master in this case was biased against petitioners, and that we should not permit him to "shield his actions from appellate review." In support of her argument, Lombardi cites scores of unrelated decisions

rendered by the special master assigned to this case. We conclude that those decisions are irrelevant to the case before us and that Lombardi's allegations against the special master are misplaced. There is a difference between disagreement with a special master's fact findings and an accusation that he is biased against petitioners. We have stated before that special masters of the Claims Court have "the unenviable job of sorting through these painful cases and . . . judging the merits of the individual claims." *Hodges v. Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). The special master spent significant effort in deciding Lombardi's case, holding three separate hearings, analyzing Lombardi's extensive medical record, resolving conflicting expert opinions, and reviewing a gamut of evidentiary materials submitted by both parties to rule on multiple factual and legal issues in a significantly difficult case. The Claims Court affirmed his judgment, holding his factual findings to be reasonable and his conclusions in accordance with the law. We agree with the Claims Court. Contrary to Lombardi's assertion, the special master did not "cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." *Andreu*, 569 F.3d at 1374.

To the extent that Lombardi urges us to independently evaluate the facts of this case to decide whether she suffers from any of the medical conditions that she alleges, we are not at liberty to do so. The special master's opinion in this case was well reasoned and put forth a thorough analysis of each of Lombardi's claims. We cannot second guess the special master's fact conclusions. *Hodges*, 9 F.3d at 961 ("The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Master's fact-intensive conclusions.").

This is an unfortunate case. Lombardi obviously had a multitude of symptoms of illness. Whether any of them was caused by hepatitis B vaccine we do not know. But, having carefully reviewed Lombardi's arguments and the record in this case, we conclude that the special master's determination that Lombardi had failed to prove by a preponderance of evidence that she suffered from any of the three claimed medical conditions and that she is entitled to compensation under the Vaccine Act was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B); *Hines*, 940 F.2d at 1524.

CONCLUSION

We have considered Lombardi's remaining arguments and do not find them persuasive. Accordingly, the judgment of the Claims Court is

AFFIRMED.

COSTS

No Costs.

United States Court of Appeals for the Federal Circuit

CHERYL LOMBARDI,
Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

2011-5004

Appeal from the United States Court of Federal Claims in Case No. 99-VV-523, Judge Marion Blank Horn.

O'MALLEY, *Circuit Judge*, concurring.

Because the majority correctly applies the standard set forth in *Broekelschen v. Secretary of Health & Human Services*, 618 F.3d 1339 (Fed. Cir. 2010), and because we are bound by this court's precedent, I concur in the judgment of the court. I write separately, however, to question whether *Broekelschen* articulates the appropriate standard, particularly since it marks a departure from this court's prior holding in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005).

In *Althen*, this court explained that a claimant seeking compensation for an off-Table injury must show that

the "vaccination caused her malady." 418 F.3d at 1278. Specifically, the court set forth the following three-part test for causation:

> [The petitioner's] burden is to show by preponderant evidence that the vaccination brought about her 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.

Id. A claimant who satisfies this burden is entitled to compensation unless the government can prove, by a preponderance of the evidence, that the claimant's injury is due to factors unrelated to the vaccine. *Id.*

In *Broekelschen*, the court added an additional hurdle not contemplated in *Althen*. Specifically, the court held that, where the parties dispute the existence and nature of the injury, the special master must first determine which injury is best supported by the evidence before applying the *Althen* test to determine whether the vaccine caused that injury. *Broekelschen*, 618 F.3d at 1346. After *Broekelschen*, therefore, "identifying the injury is a prerequisite to the [causation] analysis." *Id.*

Judge Mayer, who wrote the unanimous opinion in *Althen*, dissented in *Broekelschen* on grounds that the majority's approach of "first assigning a diagnosis to [the petitioner's] symptoms before applying the *Althen* test, is not supported by statute, caselaw, or logic, and its effect was to impermissibly heighten [the petitioner's] burden." *Broekelschen*, 618 F.3d at 1352. As Judge Mayer explained, the Vaccine Act does not "narrowly limit[] its application to known injuries." *Id.* Instead, by its terms, the Vaccine Act: (1) creates a cause of action for persons

suffering from a "vaccine-related injury or death"; and (2) broadly defines "vaccine-related injury or death" to include "an illness, injury, condition, or death." *See* 42 U.S.C. § 300aa-11(c); 42 U.S.C. § 300aa-33(5).

According to the majority in *Broekelschen*, "[m]edical recognition of the injury claimed is critical and by definition a 'vaccine-related injury,' i.e., illness, disability, injury or condition, has to be more than just a symptom or manifestation of an unknown injury." 618 F.3d at 1349. In effect, the majority in *Broekelschen* suggests that a claimant must prove that she has received a firm diagnosis of a specific disease or disorder before the methodology of *Althen* is to be applied. And, the majority in *Broekelschen*, as the majority here, makes clear that where there is a question as to the precise nature of the injury, the special master virtually has free reign to choose from among the possible diagnoses. I disagree with these requirements.

By statute, an off-Table petitioner, such as Lombardi, must allege only that she "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a Vaccine." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Although the claimant must show that the vaccine caused an "illness, disability, injury, or condition," nothing in the statutory language requires a clear diagnosis. Indeed, the breadth and variety of the phrases chosen to describe the possible harms cognizable under the Act implies that no such requirement should be read into the statute. Given the absence of a diagnosis requirement, I agree with Judge Mayer that, even where there is no "definitively diagnosed injury," a petitioner "may experience an illness or disability that, with the proper showing of causation, can meet the criteria for a vaccine-related injury under the Vaccine Act." *See Broekelschen*, 618 F.3d at 1352.

The majority in *Broekelschen* emphasized that this situation, where the exact nature of the injury is disputed, is "atypical" and "unusual." 618 F.3d at 1349. Similarly, the special master here stated that Lombardi's case is "unusual" because: (1) "doctors have not reached any consensus about what condition affects her now, or affected her in 1997-98"; and (2) her "treating doctors have not diagnosed her with one condition consistently." *Doe 60 v. Sec'y of Health & Human Servs.*, No. 99-VV-523, 2010 WL 1506010, *7 (Fed. Cl. Mar. 26, 2010). As Judge Mayer noted in his dissent, however, *every* case is unique, and it is not difficult to imagine cases such as this, where medical examiners agree that something is wrong with an individual but either disagree as to the exact diagnosis or simply arrive at different, non-conflicting diagnoses. Importantly, nothing in the terms of the Vaccine Act requires a petitioner to show agreement among experts as to a specific diagnosis.

Broekelschen marks an unwarranted departure from this court's decision in *Althen* and provides a mechanism for special masters to shortcut the causation analysis in instances where the alleged injuries can support multiple diagnoses. As long as the respondent suggests an alternate diagnosis, the special master can effectively render his own diagnosis and deny compensation without ever shifting the burden to the government to show, by a preponderance of the evidence, that other factors unrelated to the vaccine caused the injury. As this court has recognized, however, the purpose of the Vaccine Act "was to establish a compensation program under which awards could be made to vaccine-injured persons 'quickly, easily, and with certainty and generosity.'" *Shyface v. Sec'y of Heath & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir. 1999) (quoting H.R. Rep. No. 99-908, 99th Cong., 2d Sess. (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344). Because

Broekelschen creates an additional prerequisite to recovery and impermissibly increases a petitioner's burden, I believe its holding contravenes the purpose of the Vaccine Act and is inconsistent with both the statutory language and our prior decision in *Althen*.

Accordingly, although I agree that the decision in this case is correct in light of *Broekelschen*, and therefore concur in the court's judgment, I question whether that case articulates the correct standard. For the reasons discussed above, I believe we should revisit or significantly limit our decision in *Broekelschen*.