

United States Court of Appeals for the Federal Circuit

JENNIFER LOCANE,
Petitioner-Appellant,

v.

**SECRETARY OF HEALTH AND HUMAN
SERVICES,**
Respondent-Appellee.

2011-5131

Appeal from the United States Court of Federal Claims in Case No.99-VV-589, Judge Christine O.C. Miller.

Decided: July 12, 2012

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

MELONIE J. MCCALL, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee. Of counsel on the brief were TONY WEST, Assistant Attorney General, MARK W. ROGERS, Acting Director, VINCENT J. MATANOSKI, Acting Deputy Director, and CATHARINE E. REEVES, Assistant Director.

Before NEWMAN, PLAGER, and WALLACH, *Circuit Judges*.
WALLACH, *Circuit Judge*.

Ms. Jennifer Locane (“Ms. Locane”) filed a petition for compensation under the National Childhood Vaccine Injury Act (“Vaccine Act”), 42 U.S.C. §§ 300aa-1 to -34 (2006), alleging that she suffered Crohn’s disease as a direct result of hepatitis B vaccination. Special Master Christian J. Moran denied the claim, finding Ms. Locane’s disease began before her vaccination and finding that Ms. Locane failed to prove by a preponderance of the evidence that the vaccine caused or significantly aggravated her disease. *See Locane v. Sec’y of Health & Human Servs.*, 99 Fed. Cl. 715 (2011). Because the Court of Federal Claims (“Claims Court”) correctly concluded that the Special Master’s decision was not arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, we *affirm*.

BACKGROUND

I.

Ms. Locane was born on July 14, 1983. She was adopted and does not know the medical history of her biological family. Through age ten, Ms. Locane had typical childhood illnesses and injuries and maintained an average growth rate, with height and weight in the fiftieth percentile for children her age. However, in early adolescence Ms. Locane’s growth rate began to diminish. At thirteen she was in the twenty-fifth percentile for height and fifteenth percentile for weight, and one year later she fell to the tenth percentile for weight although she remained in the twenty-fifth percentile for height.

On August 29, 1997, her pediatrician, Dr. Tanis, did a routine examination necessary for her participation in high school athletics and administered the first of three doses of hepatitis B vaccine. Within two weeks, Ms. Locane suffered stomach cramps, loose stools, nausea, and decreased appetite. Her discomfort persisted, and on November 18, 1997, when Ms. Locane returned to see her pediatrician she weighed four pounds less than she had in August and was diagnosed with a virus. Ten days later, Ms. Locane returned to her pediatrician because there was blood in her stool and she had lost more weight. Dr. Tanis concluded Ms. Locane had either Crohn's disease or ulcerative colitis and referred her to Dr. Tano, a pediatric gastroenterologist.

Dr. Tano noted Ms. Locane's weight placed her below the fifth percentile for children her age. Dr. Tano opined that Ms. Locane was suffering from inflammatory bowel disease and recommended she go to the hospital. After a series of tests that showed results "consistent with Crohn's disease," she was prescribed Prednisone (a steroid) and discharged from the hospital on December 9, 1997.

On December 11, 1997, Ms. Locane was given her second dose of the hepatitis B vaccine, as well as other vaccinations, without any adverse effects. Her Prednisone prescription was adjusted over the next few weeks as her condition seemingly improved. Ms. Locane received her third dose of the hepatitis B vaccine on February 6, 1998. Shortly thereafter her condition deteriorated. In response, Dr. Tano increased her Prednisone prescription on March 16, 1998.

II.

Ms. Locane filed her petition in the Claims Court on August 4, 1999, but development of the case was put on

hold as the parties attempted to establish a mechanism for cases involving the hepatitis B vaccine. A Special Master was assigned to the case on February 8, 2006, and expert testimony was heard on April 17, 2008.

Ms. Locane argued that the hepatitis B vaccine caused her Crohn's disease and/or caused significant aggravation to her condition. Ms. Locane testified that she had no intestinal problems before her August 1997 hepatitis B vaccination. She attributed the fact that she had no reaction to the second vaccination in December 1997 to her high dosage of Prednisone at the time. Ms. Locane described the consequences of her Crohn's disease, which included multiple protracted hospital visits throughout college.

As a preliminary step, the Special Master held that it was necessary to resolve when Ms. Locane's Crohn's disease began. Ultimately, the Special Master concluded that the preponderance of the evidence proved Ms. Locane had Crohn's disease before her August 1997 vaccination and therefore the vaccination could not have caused her Crohn's disease.

Dr. Bellanti, Ms. Locane's expert, is a professor of immunology. Dr. Bellanti testified that there is a clear temporal relationship between the hepatitis vaccination and Ms. Locane's development of Crohn's disease, and that theoretically a vaccination could cause Crohn's disease.

The Secretary of Health and Human Services's expert, Dr. Warner, is a clinical professor who specializes in Crohn's disease. Dr. Warner dismissed the temporal relationship between receipt of the hepatitis B vaccine and the diagnosis of Crohn's disease as coincidental. Instead, Dr. Warner pointed to Ms. Locane's reduced growth velocity, as evidenced in her growth charts, as an

indication that she had Crohn's disease prior to receiving the hepatitis B vaccine. Dr. Warner explained that “[a] reduction in growth velocity is commonly the first sign of Crohn's disease seen in the pediatric population, with gastrointestinal symptoms manifesting at a later date.” *Locane*, 99 Fed. Cl. at 721. On cross examination, Dr. Bellanti recognized that “a decrease in growth velocity may be the first sign of Crohn's disease.” *Id.* at 722.

The Special Master deemed Dr. Warner's testimony more persuasive than Dr. Bellanti's given the extent of Dr. Warner's experience and expertise with Crohn's disease and given that his testimony was consistent with the medical literature:

The special master found that petitioner offered “little response” to Dr. Warner's opinion that petitioner's weight velocity decreased prior to her Crohn's diagnosis The special master explained that petitioner's argument that her pre-vaccination health was normal because she was a petite child and lost only a few pounds from age of eleven to thirteen was not supported by the “relevant measure,” which is the “rate of change, not the absolute weight.”

Id. The Special Master gave credit to Dr. Warner's explanation that Ms. Locane's treating doctors failed to diagnose her Crohn's disease until after the vaccinations because it is easy to miss the subtle early symptoms. The Special Master found that because the average delay in diagnosis was 13.7 months, Ms. Locane's 16 month lapse between her growth velocity decreasing and her gastrointestinal symptoms was not out of the ordinary.¹ Having

¹ The Special Master also considered and rejected the expert opinion of Dr. Solny, another gastroenterologist. Dr. Solny's first report was discounted because he

found Ms. Locane's disease began before her vaccination, the Special Master held that the vaccine could not have caused the disease and an analysis under *Althen* was unnecessary. *See Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (summarizing the elements necessary to show by preponderant evidence that the vaccination brought about a petitioner's injury).

The Special Master then determined that Ms. Locane failed to show by a preponderance of the evidence that she was entitled to compensation under the significant aggravation theory because the course of her disease was not affected by the vaccination. The Special Master found that flare-ups in symptoms are part of the normal course of the disease, that Ms. Locane did not have an adverse reaction to the second vaccination dose, and that she experienced flare-ups throughout college that were not preceded by a hepatitis B vaccination. Therefore, the Special Master found Ms. Locane did not show that her condition was worse than it would have been but for the vaccination.

On review, the Claims Court affirmed, concluding that the Special Master's factual finding that the onset of Ms. Locane's Crohn's disease occurred prior to her hepatitis B vaccination was not arbitrary or capricious. Furthermore, the Claims Court held that failure to conduct an analysis under *Althen* after determining that the preponderance of evidence showed the illness predates the vaccination was not an abuse of discretion. Finally, the

had mistakenly assumed that Ms. Locane received her first hepatitis B vaccination in 1994 and sometime thereafter her growth velocity slowed. Dr. Solny's second report failed to address the change in Ms. Locane's growth curve and failed to address Dr. Warner's opinion that Ms. Locane suffered from Crohn's disease prior to her August 1997 vaccination.

Claims Court held that the Special Master's factual finding that Ms. Locane failed to prove significant aggravation was not arbitrary or capricious.

Ms. Locane timely appealed to this court. We have jurisdiction over this appeal pursuant to 42 U.S.C. § 300aa-12(f).

DISCUSSION

"We review an appeal from the Court of Federal Claims in a Vaccine Act case *de novo*, applying the same standard of review as the Court of Federal Claims applied to its review of the special master's decision." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010). We give no deference to the Claims Court's or Special Master's determinations of law, but uphold the Special Master's findings of fact unless they are arbitrary or capricious. *Id.*

To receive compensation under the Vaccine Act a petitioner must prove by a preponderance of the evidence that the injury at issue was caused by a vaccine. 42 U.S.C. § 300aa-13(a)(1). Causation is presumed if a petitioner can show that she sustained an injury in association with a vaccine listed in the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(C)(i); *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009). If the injury is not listed in the Vaccine Injury Table, a petitioner must prove actual causation or causation in fact by a preponderance of the evidence. 42 U.S.C. § 300aa-11(c)(1)(C)(ii); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010). There is a three prong test to demonstrate causation in fact "by preponderant evidence"; the petitioner must provide: "(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. Upon demonstration of causation a petitioner is entitled to compensation unless the respondent “can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine.” *Broekelschen*, 618 F.3d at 1342; *see* 42 U.S.C. § 300aa-13(a)(1)(B). Additionally, a petitioner can receive compensation if a vaccination “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” the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Significant aggravation is defined as “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” 42 U.S.C. § 300aa-33(4).

I.

Ms. Locane argues that the Special Master’s determination that the onset of her Crohn’s disease occurred prior to her first hepatitis B vaccination was arbitrary and capricious. Ms. Locane asserts that her treating physicians took no notice of her weight prior to her vaccination, that her significant weight loss occurred after August 1997, and that prior to that time “there was no manifestation of symptoms that justified a diagnosis of Crohn’s.” Ms. Locane contends that Dr. Warner’s explanation is equivocal, that the medical records and actions of her treating doctors demonstrate the onset of her Crohn’s disease came after her vaccination, and that any close calls should be resolved in her favor, and therefore, denial of her claim was arbitrary and capricious.²

² Specifically, Ms. Locane objects to the significance placed on Dr. Warner’s testimony that she had fallen “off of the growth curve” prior to her vaccination when her

“Expert medical testimony is often very important in Vaccine Act cases based on off-Table injuries The special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories.” *Broekelschen*, 618 F.3d at 1347; see *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000) (we give deference to the Special Master’s factual findings, which are “virtually unchallengeable on appeal”). The Special Master found Dr. Warner’s testimony more persuasive than Dr. Bellanti’s because of their different backgrounds and specialties and because the medical literature supports Dr. Warner’s theory. *Locane*, 99 Fed. Cl. at 721-22. We find nothing arbitrary or capricious about the Special Master’s determination that Dr. Warner’s testimony was more persuasive than Dr. Bellanti’s testimony. Accordingly, we affirm the Claims Court’s decision to uphold the Special Master’s finding that the onset of Ms. Locane’s illness began prior to her hepatitis B vaccination. See *Hodges v. Sec’y of Dep’t of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (noting the reviewing court’s purpose “is not to second guess the Special Master[s] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process”).

II.

weight loss was insubstantial until after August 1997. Also, Ms. Locane argues that her weight loss did not reach the range the medical literature cites as an early manifestation of the disease (4.52 kg to 22.6 kg) until after her first hepatitis B vaccination. Furthermore, Ms. Locane notes that no one was concerned about the initial decreases in growth velocity, that none of her treating doctors identified the onset as prior to her vaccination, and that one of her doctors even filed a Vaccine Adverse Event Reporting System report indicating a “suspected reaction” to the vaccination.

Ms. Locane also contends that the Special Master erred in failing to conduct an analysis under *Althen*. She avers that she has met her burden of proving causation by presenting a medical theory that causally connects the vaccination and the injury, by demonstrating a medically appropriate temporal association between the vaccination and the onset of her illness, and by establishing a logical sequence of cause and effect.

In *Althen*, this court enunciated the standard for determining when a petitioner has met her burden of showing by preponderant evidence that the vaccine caused the injury. *Althen*, 418 F.3d at 1278. The three-prong test is intended to evaluate whether the vaccine actually caused the injury. To prove causation in fact “by preponderant evidence” a petitioner must demonstrate: “(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.* Given the Special Master’s finding that the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness. The *Althen* inquiry is inapplicable.³ Accord-

³ This court has previously discussed instances where it is appropriate for the Special Master to first determine an injury before applying the *Althen* test. In *Broekelschen* the court held “it was appropriate for the special master to initially determine which injury Dr. Broekelschen suffered before applying the *Althen* test.” *Broekelschen*, 618 F.3d at 1349. In *Althen* this court stated that “[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, [to] meet the burden of showing actual causation.” *Althen*, 418 F.3d at 1278. In the case at hand, the appearance of symptoms

ing to 42 U.S.C. § 300aa-13(a)(1)(B) compensation should only be awarded if on the record as a whole “there is not a preponderance of the evidence that the illness . . . is due to factors unrelated to the administration of the vaccine” As the Claims Court explained, “[n]owhere in the statutory scheme or Federal Circuit precedent emerges a requirement that the special master conduct a causation analysis once the special master has determined that a preponderance of the evidence shows that the onset of the illness predates the vaccination.” *Locane*, 99 Fed. Cl. at 729.

III.

In the alternative, Ms. Locane argues that if “contrary to all evidence” the court upholds the finding that her Crohn’s disease was preexisting, then the course of her disease was significantly aggravated by her hepatitis B vaccinations. Ms. Locane notes that “there is not a single expected course of Crohn’s disease,” and prior to the vaccination she had no other symptoms except for some mild weight fluctuations and the illness “did not in any way impact her life.” Ms. Locane acknowledges that there is no known cause of Crohn’s disease, but posits numerous plausible theories “along with a demonstrated striking temporal association of onset, or in the instance of significant aggravation, flare-ups following vaccination within a medically appropriate time-frame.”

The Special Master held that “a preponderance of the evidence demonstrates that [Ms. Locane’s] course was consistent with Crohn’s disease and was not affected by the hepatitis B vaccination.” *Locane*, 99 Fed. Cl. at 731. The testimony was unclear as to whether Crohn’s has a specific pattern or normal course. The Special Master

after vaccination does not necessitate a finding of causation.

credited Dr. Warner’s testimony that it was typical for young people to experience flare-ups with Crohn’s disease like those Ms. Locane experienced and found Ms. Locane’s expert evidence did not persuasively show the vaccination made her symptoms worse. *Id.* The Special Master concluded that “something other than the hepatitis B vaccine cause[d] [Ms. Locane] to suffer worse symptoms of Crohn’s disease” given that she did not experience a flare-up after the second vaccination and she experienced similar flare-ups that were not preceded by a vaccination dose. *Id.* at 732. Ultimately, the Special Master found that the preponderance of the evidence showed that the course of Ms. Locane’s condition was not inconsistent with the disease generally and not affected by the vaccinations. *Id.* at 733. Because the Special Master “considered the relevant evidence of record, [drew] plausible inferences and articulated a rational basis for the decision,” the decision was not arbitrary or capricious. *Hines v. Sec’y of Dep’t of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). Ms. Locane was given ample opportunity to develop her significant aggravation claim but “failed to present persuasive evidence that separates [her] problems from an expected course of Crohn’s disease.” *Locane*, 99 Fed. Cl. at 731 (quoting *Locane v. Sec’y of Health & Human Servs.*, No. 99-589V (Fed. Cl. Spec. Mstr. Feb. 17, 2011)). It is not the role of this court to relitigate claims that have already been adjudicated. Accordingly, we affirm the Claims Court’s decision that Ms. Locane failed to prove significant aggravation.

CONCLUSION

The decision of the Claims Court upholding the Special Master’s denial of compensation under the Vaccine Act is affirmed.

AFFIRMED

No costs.