United States Court of Appeals for the Federal Circuit

PETER BROEKELSCHEN, M.D.,
Petitioner-Appellant

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

2009-5132

Appeal from the United States Court of Federal Claims in case no. 07-VV-137, Judge George W. Miller.

Decided: September 10, 2010

LISA A. ROQUEMORE, Broker & Associates, PC, of Irvine, California, argued for petitioner-appellant.

VORIS E. JOHNSON, JR., Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee. With him 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 GAJARSA, MAYER, and PLAGER, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* GAJARSA.

Dissenting Opinion filed by *Circuit Judge* MAYER.

GAJARSA, *Circuit Judge*.

Peter Broekelschen, M.D., appeals the decision of the United States Court of Federal Claims affirming a special master's decision denying Dr. Broekelschen's petition for compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34 (2006). The special master concluded that Dr. Broekelschen did not prove by a preponderance of the evidence that the flu vaccine caused his injury. *See Broekelschen v. Sec'y of Health & Human Servs.*, 89 Fed. Cl. 336 (2009). Because the Court of Federal Claims 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.

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). A petitioner can show causation under the Vaccine Act in one of two ways. Either the petitioner can prove causation by showing that she sustained an injury in association with a vaccine listed in the Vaccine Injury Table ("Table injury"). *Id.* § 300aa-11(c)(1)(C)(i). In such a case, causation is presumed. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009). Or, if the complained-of 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); *see also* 42 U.S.C. § 300aa-11(c)(1)(C)(ii). Once the petitioner has demonstrated causation, she is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine. *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1351 (Fed. Cir. 2010); *see also* 42 U.S.C. § 300aa-13(a)(1)(B).

II.

On October 28, 2005, Dr. Broekelschen received a flu vaccine. At the time he received the flu vaccine, Dr. Broekelschen was sixty-three years old and was in excellent health. He had an active medical practice in gastroenterology working about sixty hours a week. In addition, Dr. Broekelschen enjoyed an active lifestyle spending most weekends jogging, bicycling, swimming, kayaking, or skiing.

On December 16, 2005, while at work, Dr. Broekelschen developed crushing pain in his chest that spread to his arms, fingers, neck, and around his left scapula. Dr. Broekelschen was transported by ambulance to Hoag Memorial Hospital Presbyterian and admitted that same day. Doctors first performed multiple electrocardiograms ("EKGs") to test Dr. Broekelschen's heart activity, which appeared normal, thus ruling out a heart attack. Doctors then performed Magnetic Resonance Imaging ("MRI") revealing degenerative changes in the cervical spine. Additional MRIs revealed two lesions, one in the cervical spine (C2-C3 level) and one in the thoracic spine (T2 level). Doctors also performed an angiogram revealing an occlusion of the anterior spinal artery at the C2-C3 level. While Dr. Broekelschen was hospitalized, he required an emergency bladder catheterization due to paralysis in his

bladder and bowels. Doctors took a cerebrospinal fluid sample that revealed normal levels of Immunoglobulin G ("IgG"), one white blood cell, and an elevated protein count. According to Dr. Jacob P. Verghese, the doctor who discharged Dr. Broekelschen, Dr. Broekelschen's proprioception was unaffected. Proprioception is the ability to sense the position, location, orientation, and movement of one's body and its parts. But Dr. Broekelschen testified that a neurologist visited him while he was hospitalized and concluded that Dr. Broekelschen's proprioception was abnormal.

While Dr. Broekelschen was hospitalized, the differential diagnoses included anterior spinal artery syndrome or transverse myelitis, possibly due to the flu vaccine. Anterior spinal artery syndrome is a vascular event caused by an occlusion or blockage in the anterior spinal artery, reducing blood flow, that disrupts neurological activity only on the anterior side of the spinal column. Transverse myelitis is a neurological disorder caused by an abnormal immune response resulting in inflammation across both sides of one level of the spinal cord that interrupts communications between the nerves in the spinal cord and the rest of the body. Ultimately, Dr. Verghese concluded in a discharge summary that Dr. Broekelschen suffered from cervical myelopathy, etiology unknown. Cervical myelopathy is a general term referring to dysfunction of the spinal cord caused by one of many diseases including anterior spinal artery syndrome and transverse myelitis.

More than three months after Dr. Broekelschen was hospitalized, he was examined by various doctors in an effort to determine the proper diagnosis. Dr. Stanley vanden Noort, a neurologist, and Dr. John C. Storch, Dr. Broekelschen's primary care physician, both examined Dr. Broekelschen and concluded that he suffered from trans-

verse myelitis secondary to the flu vaccine. However, Dr. Storch wrote "there is no test available to prove this" and his conclusion was made "in the absence of another working diagnosis." J.A. 119. Dr. vanden Noort observed that Dr. Broekelschen's proprioception was affected in his left foot and simply stated that "[o]ur neuroradiologists concur with the report of transverse myelitis." J.A. 117. Dr. vanden Noort, however, concluded that "[i]t is not necessary to pursue alternative diagnoses because [Dr. Broekelschen] is improving slowly." *Id.*

Despite Dr. vanden Noort and Dr. Storch's conclusions, Dr. Broekelschen presented symptoms that are characteristic of both anterior spinal artery syndrome, a vascular condition, and transverse myelitis, an inflammatory response. Both injuries can cause severe neck or lower back pain and paralysis of the bladder, bowels, and extremities. One distinguishing symptom, however, is that proprioception is affected in transverse myelitis, but not in anterior spinal artery syndrome. In addition, if a patient suffers from transverse myelitis, doctors would typically observe elevated levels of white blood cells and IgG in the cerebrospinal fluid because transverse myelitis is often caused by an immune response. On the other hand, if a patient suffered from anterior spinal artery syndrome, an angiogram, which is a visualization of blood flow, would evidence an occlusion in the anterior spinal artery.

III.

Dr. Broekelschen filed a petition in the Court of Federal Claims seeking compensation under the Vaccine Act alleging that the flu vaccine caused him to suffer transverse myelitis. *See Broekelschen v. Sec'y of Health & Human Servs.*, No. 07-137V, 2009 U.S. Claims LEXIS 137 (Fed. Cl. Feb. 4, 2009) (special master's published decision

denying entitlement). The case was assigned to a special master from the Court of Federal Claims. Because transverse myelitis is an off-Table injury, Dr. Broekelschen was required to prove causation in fact. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(ii).

Both parties retained well-qualified experts, who submitted reports and testified at a hearing held by the special master regarding whether the flu vaccine caused Dr. Broekelschen's injury. Dr. Lawrence Steinman, Dr. Broekelschen's expert, is a Board Certified Neurologist, a Professor of Neurology and Pediatrics, and chair of the Program in Immunology at Stanford University. He has over thirty years of medical experience in neurology and has dealt with transverse myelitis as a result of vaccinations several times a year as either a treating physician or in departmental conferences. Dr. Steinman has served on expert and advisory panels relating to vaccination matters as well as received various awards for research on the nervous system. He has also authored over 300 articles relating to how the immune system attacks the nervous system with about twenty articles directly dealing with vaccines. Dr. Steinman opined that the flu vaccine caused Dr. Broekelschen to suffer transverse myelitis.

Dr. Benjamin Greenberg, the government's expert, disagreed and opined that Dr. Broekelschen suffered from anterior spinal artery syndrome, which was not caused by the flu vaccine. At the time of the hearing, Dr. Greenberg was an assistant professor in the Department of Neurology at Johns Hopkins School of Medicine. Dr. Greenberg was also the co-director of the Johns Hopkins Transverse Myelitis Center, the only center in the world dedicated to transverse myelitis. As of July 2007, the Johns Hopkins Transverse Myelitis Center had seen over 1200 patients with spinal cord disease. Also, the Transverse Myelitis Center has done extensive research on the diagnosis,

treatment, and long-term care of patients with transverse myelitis. As a result of his position, Dr. Greenberg worked with patients suffering from transverse myelitis on a daily basis.

On February 4, 2009, the special master published a detailed explanation for his decision denying Dr. Broekelschen entitlement under the Vaccine Act. *Broekelschen*, 2009 U.S. Claims LEXIS 137, at *1. Because there was a dispute between the parties regarding Dr. Broekelschen's alleged injury, the special master considered as a primary matter which injury, transverse myelitis or anterior spinal artery syndrome, was best supported by the record. *Id.* at *11. The special master conducted a thorough analysis of all the tests performed on Dr. Broekelschen, opinions of treating physicians, records after discharge, and the conflicting opinions of the testifying experts. *See id.* at *18–57. The special master found that "[f]or virtually every point in favor of one diagnosis, there is a point in favor of the other diagnosis." *Id.* at *45. Thus, the special master considered each piece of evidence and explained why it supported a finding of transverse myelitis or anterior spinal artery syndrome.

The special master also considered the relative weight of the testifying experts. The special master found Dr. Greenberg, the government's expert, to be more persuasive. *Id.* at *49–50. He based his decision in large part on Dr. Greenberg's specialization while working at the Johns Hopkins Transverse Myelitis Center, the only center in the world devoted to transverse myelitis. *Id.* In addition, Dr. Greenberg's report and testimony incorporated all of the evidence, whereas Dr. Steinman disregarded an important piece of evidence, the angiogram, which showed an occlusion in the anterior spinal artery. *Id.* at *56. The special master also indicated that Dr. Greenberg's "demeanor suggested that he was attempting to provide the

basis for his opinion as forthrightly as possible." *Id.* at *36. The special master concluded that "the weight of the entire record—including (but not limited to) the angiogram, the MRIs, the finding regarding proprioception, the statements of treating doctors, and the testimony of Dr. Broekelschen, Dr. Steinman and Dr. Greenberg—indicates that Dr. Broekelschen suffered anterior spinal artery syndrome." *Id.* at *56.

After the special master found that anterior spinal artery syndrome was the injury best supported by the evidence, the special master considered whether Dr. Broekelschen had shown by a preponderance of the evidence that the flu vaccine had actually caused his anterior spinal artery syndrome. *Id.* at *57–65. The special master found that Dr. Broekelschen had not shown by preponderant evidence "a medical theory causally connecting the vaccination and [anterior spinal artery syndrome]," *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), and therefore Dr. Broekelschen had not shown by a preponderance of the evidence that the flu vaccine caused his injury. *Broekelschen*, 2009 U.S. Claims LEXIS 137, at *65–66.

IV.

Dr. Broekelschen sought review of the special master's decision in the Court of Federal Claims. *See Broekelschen*, 89 Fed. Cl. at 336. The Court of Federal Claims affirmed the special master's decision, finding that the special master properly considered the entire record. *Id.* at 346. Contrary to Dr. Broekelschen's argument, the court found that the experts' demeanor was only "one factor among many," *id.*, and that the special master's credibility determination of the experts was "'virtually unchallengeable on appeal,'" *id.* at 345 (quoting *Lampe v.*

Sec'y of Health & Human Servs., 219 F.3d 1357, 1362 (Fed. Cir. 2000)).

Dr. Broekelschen 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 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. *Andreu*, 569 F.3d at 1373. We owe no deference to the trial court or special master on questions of law. *Id.* 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 Court of Federal Claims under a non-deferential standard, we are in effect reviewing the decision of the special master under the deferential and capricious standard on factual issues." *Lampe*, 219 F.3d at 1369.

I.

When a petitioner has suffered an off-Table injury, as is the case here, this court has 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. Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). "[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*, 35 F.3d at 549).

Dr. Broekelschen argues that the special master erred by not first determining whether Dr. Broekelschen established a prima facie case that the vaccine caused the alleged transverse myelitis injury before determining that Dr. Broekelschen suffered from anterior spinal artery syndrome, an alternate cause unrelated to the vaccine. The petitioner makes an argument by analogy to the statutory scheme provided by the Vaccine Act where a petitioner is entitled to recover once she has shown by a preponderance of the evidence that the vaccine caused her injury, "unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.'" *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007) (quoting *Whitecotton v. Sec'y of Health & Human Servs.*, 17 F.3d 374, 376 (Fed. Cir. 1994), *rev'd on other grounds sub nom.*, *Shalala v. Whitecotton*, 514 U.S. 268 (1995)). But the instant action is atypical because the injury itself is in dispute, the proposed injuries differ significantly in their pathology, and the question of causation turns on which injury Dr. Broekelschen suffered.

Therefore, it was appropriate in this case for the special master to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test so that the special master could subsequently determine causation relative to the injury.

The Act creates a cause of action for persons suffering a "vaccine-related injury," *see* 42 U.S.C. § 300aa-11(c), and identifies the injuries commonly associated with each vaccine in the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-14; 42 C.F.R. § 100.3(a). An off-Table petitioner, who does not benefit from a presumption of causation, must specify his vaccine-related injury and shoulder the burden of proof on causation. *Id.* Also, a careful reading of *Althen*, shows that each prong of the *Althen* test is decided relative to the injury: (1) medical theory connecting the vaccination to the *injury*; (2) cause and effect showing the vaccination was the reason for the *injury*; and (3) proximate temporal relationship between the vaccination and the *injury*. *See Althen*, 418 F.3d at 1278; *Doe*, 601 F.3d at 1351. Thus, identifying the injury is a prerequisite to the analysis.

Moreover, while the two conditions—transverse myelitis and anterior spinal artery syndrome—have overlapping symptoms, their underlying causes or etiology are completely different. *Cf. Andreu*, 569 F.3d at 1378, 1381 (noting that an exact diagnosis was not required to determine whether the DPT vaccine caused the injury because while the parties disputed whether the petitioner suffered a febrile or afebrile seizure, both parties agreed that "whatever caused [the petitioner's] first seizure led to his subsequent seizure disorder"); *Kelley v. Sec'y of Health & Human Servs.*, 68 Fed. Cl. 84, 100–01 (2005) (finding that the petitioner was not required to categorize his injury where the two possible diagnoses were "variants of the same disorder, as their pathologic features might

suggest"). Transverse myelitis is an inflammatory event caused by an immune response, whereas anterior spinal artery syndrome is a vascular event caused by a blockage. Dr. Broekelschen presented with symptoms common to both transverse myelitis and anterior spinal artery syndrome, and the parties dispute which disease Dr. Broekelschen suffered. This is unlike *Andreu*, where the parties agreed that the petitioner suffered from a seizure disorder, *see* 569 F.3d at 1378, 1381, or *Kelley*, where the competing diagnoses were variants of the same disorder, 68 Fed. Cl. at 100–01. Here, nearly all of the evidence on causation was dependent on the diagnosis of Dr. Broekelschen's injury. Therefore, it was appropriate for the special master to first find which of Dr. Broekelschen's diagnoses was best supported by the evidence presented in the record before applying the *Althen* test so that the special master could subsequently determine causation relative to the injury. Accordingly, we review each finding in turn.

II.

The special master's opinion reveals a thorough and careful evaluation of all the evidence to ascertain which injury is best supported by the record. *See Broekelschen*, 89 Fed. Cl. at 341—46. "He divided the evidence into four categories: tests; clinical symptoms, including proprioception; opinions of treating doctors; and opinions of testifying experts." *Id.* at 341. He found that certain evidence, such as the medical records and doctors' notes, were not as persuasive as other evidence because the treating doctors were "not consistent in their diagnoses." *Broekelschen*, 2009 U.S. Claims LEXIS 137, at *43. Furthermore, the special master noted that the doctors in their post-hospitalization notes did "not provide any reasoning for their statements." *Id.* at *31. Rather, the special master found the discharge summary written by Dr.

Verghese more persuasive because Dr. Verghese was very familiar with Dr. Broekelschen's experience while in the hospital and was able to consider all of the medical records. *Id.* at *28–30, *32; *see also Capizzano*, 440 F.3d at 1326 ("[T]reating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect shows that the vaccination was the reason for the injury.'" (quoting *Althen*, 418 F.3d at 1280)). Dr. Verghese, in a detailed discharge summary, stated that the "diagnosis has not been clearly established" and the etiology was unknown. J.A. 123-24. He also summarized all of the medical records and concluded that Dr. Broekelschen suffered from myelopathy—a general term encompassing both anterior spinal artery syndrome and transverse myelitis. The special master reasoned that because Dr. Verghese wrote that a diagnosis "has not been clearly established" Dr. Verghese intended to leave the question open.

Because the medical evidence was not definitive, the special master relied heavily on expert medical testimony. *Broekelschen*, 2009 U.S. Claims LEXIS 137, at *45, *56. Expert medical testimony is often very important in Vaccine Act cases based on off-Table injuries requiring proof of actual causation. *See Lampe*, 219 F.3d at 1361 ("As is often true in Vaccine Act cases based on a theory of actual causation, the expert medical testimony was important in this case."). The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories. *Id.* at 1362. As such, the special master's credibility findings "are virtually unchallengeable on appeal." *Id.* However, a special master cannot "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 1379.

The special master recognized that both experts were well-qualified, but found Dr. Greenberg's testimony to be more persuasive for three reasons. First, the special master noted Dr. Greenberg's work with patients suffering from transverse myelitis on a daily basis as the co-director of the Johns Hopkins Transverse Myelitis Center, the only center dedicated to transverse myelitis in the world. *Id.* at *34–35. Second, the special master found that Dr. Greenberg's demeanor was more persuasive as he was more forthright and independent in his responses. *Id.* at *36. Lastly, Dr. Greenberg's theory incorporated all of the evidence, whereas Dr. Steinman largely excluded one of the most important pieces of evidence, the angiogram. *Id.* at *56.

Dr. Broekelschen contends that the special master improperly used the "guise of a credibility determination" to exclude evidence that could support a finding of transverse myelitis such as the presentation of two lesions, abnormal proprioception post-hospitalization, and the reports and notes of doctors. Dr. Broekelschen places particular significance on the presence of two lesions and states that Dr. Greenberg conceded that the finding of a second lesion "is totally inconsistent with a vascular event." Petitioner's Brief at 47. Dr. Broekelschen, however, contradicts his own expert and mischaracterizes Dr. Greenberg's testimony. Dr. Steinman testified that multiple lesions "can happen" in a vascular event, albeit "far less likely." Dr. Greenberg testified that the presence of multiple lesions was as likely as "a hole-in-one on a par 5,"[1] but he went on to say, "But is it possible? *Absolutely*

[1] Indeed a hole-in-one on a par 5 is very rare. Generally, holes-in-one are seen on a par 3, which is known as an eagle. In 2001, Andrew Magee hit the only hole-in-one on a par 4—known as an albatross—on the PGA tour. A hole-in-one on a par 5—known as a condor—has only

it's possible." J.A. 837–38 (emphasis added). Dr. Broekelschen focuses heavily on Dr. Greenberg's first statement and ignores his complete testimony that multiple blockages are "absolutely" possible. *See id.* Also, Dr. Broekelschen points to the abnormal proprioception to support a finding of transverse myelitis. Yet there is no medical record that Dr. Broekelschen's proprioception was impaired while he was hospitalized; in fact, the discharge summary states that his proprioception was normal. "[R]eversible error is 'extremely difficult to demonstrate' if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'" *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)

Ironically, it is the petitioner that seems to advocate only reviewing the evidence pertaining to transverse myelitis and not the totality of the evidence presented on Dr. Broekelschen's condition. While Dr. Steinman emphasized that the MRIs indicating two lesions is inconsistent with a vascular event, he essentially ignored the angiogram showing an occlusion in the anterior spinal artery, which is highly suggestive of anterior spinal artery syndrome. Nor did Dr. Steinman try to reconcile the MRI with the angiogram. On the contrary, the special master found that Dr. Greenberg candidly acknowledged the rarity of the double lesions but persuasively explained why Dr. Broekelschen's angiogram results showing a blockage in a large artery was supportive evidence of an underlying mechanism that is vascular in nature. He testified:

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occurred four times of record and never during a professional tournament. The 'Condor'—Four Under Par for a Hole, http://www.golftoday.co.uk/golf_a_z/articles/condor.html (last visited Sep. 7, 2010).

> [E]ven when I had a patient who I would bet the farm had a vascular event in the spinal cord, it's actually rare for me to see the smoking gun. Seeing an abnormal spinal angiogram that matches with the patient's presentation, the patient's MRI, what the patient is experiencing is, again, a rarity among rarities. . . .That is a true abnormality that has to be taken seriously. And in the context of somebody who has an acute myelopathy, . . . where we did not have evidence of inflammation, then we would have actually stopped there and we would have said that we are most concerned about vascular events. That's how profound the evidence is. . . . If there was only a lesion at the cervical cord and proprioception was intact and we had that angiogram, we probably wouldn't be in this room today. I think the angiogram findings are so profound that nobody would have considered myelitis ever again.

Broekelschen, 2009 U.S. Claims LEXIS 137, at *38–39. Also, the spinal tap showed no increase in white blood cells or IgG, which is highly probative of a finding that Dr. Broekelschen did not suffer from immune-mediated transverse myelitis. Dr. Verghese concluded that the absence of inflammation "would be against [the injury] being due to a myelitis." J.A. 123. Although the hospital reports mention transverse myelitis, they also mention ischemia, which is a vascular event encompassing anterior spinal artery syndrome. The special master was presented with all the evidence and after a thorough review, he found that the evidence did not make it more likely than not that Dr. Broekelschen suffered from transverse myelitis. *Id.* at *36.

Considering all of the evidence, including medical records, tests, and reports, as well as the experts' opinions,

the special master did not require certainty or direct evidence, but rather weighed the evidence as the trier of fact and found that it was more likely that Dr. Broekelschen suffered anterior spinal artery syndrome than transverse myelitis. This court does not "reweigh the factual evidence, or [] assess whether the special master correctly evaluated the evidence. And of course we do not examine the probative value of the evidence or the credibility of the witnesses. These are all matters within the purview of the fact finder." *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 871 (Fed. Cir. 1992). Thus, the special master's determination 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.

III.

The dissent criticizes the special master's decision on two grounds. First, the dissent characterizes the special master's approach of first determining the injury before applying the *Althen* test as per se reversible error. Dissenting Op. at 3. By ignoring the atypical nature of this case, however, the dissent improperly forces this case to align with our *Althen* precedent. In most cases the injury is not disputed but this case is unusual in that the exact injury and its nature—inflammatory response or vascular event—is in dispute, and, more importantly, the causation question turns on the determination of the injury.

The Vaccine Act creates a cause of action for persons suffering a "vaccine-related injury." *See* 42 U.S.C. § 300aa-11(a). With regard to the "vaccine-related injury," a off-Table 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) . . . . " *Id.* § 300aa-11(c)(1)(C)(ii)(I). This is the same definition quoted by the dissent but it does not support its argument that proof of an "illness, condition, or disability" is something less than proof of an "injury" under the Vaccine Act. Dissenting Op. at 3. Medical 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. Thus, it was appropriate for the special master to initially determine which injury Dr. Broekelschen suffered before applying the *Althen* test.

The dissent also criticizes the special master's finding that the government's expert had a more persuasive demeanor. Dissenting Op. at 7. In general, when two expert witnesses, both highly qualified, dispute an issue of medical fact with supporting and contradictory evidence, it is immaterial whether one witness makes a better appearance on the stand. *See Andreu*, 569 F.3d at 1379; *cf. Moberly*, 592 F.3d at 1325—26 (stating that in cases where there is little supporting evidence for an expert's opinion, the special master's "[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"). Though the special master may have improperly considered Dr. Greenberg's demeanor, it was not the only factor, or even the most important factor, in the special master's analysis. To the contrary, the special master articulated a number of factors why Dr. Greenberg's medical testimony was better supported by sound medical explanation, including the fact that Dr. Greenberg's testimony candidly and forthrightly incorporated all of the evidence whereas Dr. Steinman largely excluded an important piece of adverse evidence. Thus, even if the special master's consideration of Dr. Greenberg's "demeanor" was error, it would rise at most to the level of

harmless error. *Hines*, 940 F.2d at 1526 (finding that it was harmless error for the special master to take judicial notice of a medical textbook's statement regarding the incubation period of measles, even if unfair to the petitioner, because "the special master's decision was based on a number of factors and [petitioner had] not shown that reliance on the . . . textbook was likely critical to the result").

IV.

Next, for Dr. Broekelschen to recover under the Vaccine Act, he is required to prove by a preponderance of the evidence that the flu vaccine caused his anterior spinal artery syndrome, an off-Table injury. As explained above, the *Althen* test requires that Dr. Broekelschen prove by a preponderance of the evidence: "(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.

The special master found that Dr. Broekelschen did not meet his burden of proving by a preponderance of the evidence a medical theory causally connecting the flu vaccine to anterior spinal artery syndrome. *Broekelschen*, 2009 U.S. Claims LEXIS 137, at *65; *Broekelschen*, 89 Fed. Cl. at 346. Dr. Broekelschen does not challenge this finding; rather, he argues only that anterior spinal artery syndrome is a cause unrelated to the vaccine that the special master should not have considered until Dr. Broekelschen established his prima facie case with the alleged transverse myelitis injury. As we explained above, the special master properly considered the government's alternative evidence on injury prior to determining causation. *See* 42 U.S.C. § 300aa-13(a)(1); *Doe*,

601 F.3d at 1356-58 (stating that the government can provide and the special master can consider evidence of "factors unrelated" in determining whether the petitioner established a prima facie case). Thus, the remaining question is whether, contrary to the special master's finding, Dr. Broekelschen provided proof by a preponderance of the evidence of a medical theory causally connecting the flu to anterior spinal artery syndrome.

The majority of the evidence and testimony presented by Dr. Broekelschen was directed toward proving the flu vaccine caused transverse myelitis. Dr. Steinman presented the same medical theory, molecular mimicry, for both anterior spinal artery syndrome and transverse myelitis. Dr. Greenberg pointed out, however, that the evidence relied upon for connecting the molecular mimicry theory to the flu vaccine—a literature review based on two papers from the early 1950s, which in turn considered vaccine cases between 1929 and 1952—was quite weak. Furthermore, there was little said by either party during the hearing and post-trial briefs regarding whether the flu vaccine can cause anterior spinal artery syndrome. "*Althen* makes clear that a claimant's theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu*, 569 F.3d at 1379 (quoting *Althen*, 418 F.3d at 1278). The special master found that due to the weak medical evidence presented, Dr. Broekelschen had not provided a "reliable medical or scientific explanation" sufficient to prove by a preponderance of the evidence a medical theory linking the flu vaccine to anterior spinal artery syndrome. *See Knudsen*, 35 F.3d at 548. We find that this conclusion was not arbitrary or capricious.

For the foregoing reasons, we find that the special master's determination was not arbitrary, capricious, an

abuse of discretion, or otherwise not in accordance with law. We therefore affirm.

AFFIRMED

No costs.

United States Court of Appeals for the Federal Circuit

PETER BROEKELSCHEN, M.D.,
Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee.

2009-5132

Appeal from the United States Court of Federal Claims in 07-VV-137, Judge George W. Miller.

MAYER, *Circuit Judge*, dissenting.

In my view, the special master and the Court of Federal Claims failed to properly apply our holdings in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005) and *Andreu v. Secretary of Health & Human Services*, 569 F.3d 1367 (Fed. Cir. 2009). I therefore respectfully dissent.

Peter Broekelschen received an influenza vaccination on October 28, 2005, at the age of 63. Approximately seven weeks after receiving the vaccination, on December 16, 2005, Broekelschen was hospitalized with severe pain in his chest, back, and shoulder. While in the hospital he experienced a range of symptoms, including weakness in

his extremities and sensory deficits. Doctors performed numerous tests, including several MRIs, computed tomography scans, a lumbar puncture, and an angiogram, but were unable to conclusively determine the cause of Broekelschen's symptoms. Two diagnoses considered by the treating physicians were transverse myelitis ("TM"), a condition caused by inflammation of the spinal cord, and anterior spinal artery syndrome, a condition caused by a blocked blood vessel in the spinal cord. Broekelschen was discharged on December 29, 2005, and transferred to a rehabilitation facility. His discharge summary notes that a diagnosis was not clearly established, but states that the symptoms might be due to a post-vaccine immune reaction. Several months after Broekelschen first experienced symptoms his personal physician noted that, in the absence of another working diagnosis, TM secondary to the vaccination was the most likely cause.

Broekelschen filed a petition seeking compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 to -34, alleging that his symptoms were the result of vaccination induced TM. The special master denied compensation, finding that Broekelschen did not suffer from TM but from the alternative diagnosis of anterior spinal artery syndrome and that there was insufficient evidence to support a theory that this syndrome could be caused by the influenza vaccine. Broekelschen sought review of the special master's decision in the Court of Federal Claims, which affirmed the decision of the special master denying compensation.

In *Althen*, we described the burden for a vaccine injury claimant as a three part test. In order to recover, the claimant must show by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury, (2) a logical sequence of cause and effect show-

ing the vaccination was the reason for the injury, and (3) a temporal relationship between the vaccination and the injury. 418 F.3d at 1278. If the claimant is able to make such a showing, the government is given the opportunity to show by preponderant evidence that the injury was caused by factors other than the vaccine. *Id.* In this case, the special master recognized the applicability of the *Althen* test, but decided that before applying the test it was necessary to first determine a diagnosis for Broekelschen's symptoms. The special master therefore looked at the competing theories of Broekelschen's diagnosis and determined that Broekelschen suffered from anterior spinal artery syndrome, as advanced by the government, and not TM. Only then did the special master apply the *Althen* test and determine that the evidence did not support a finding that the vaccine caused anterior spinal artery syndrome.

This approach, of first assigning a diagnosis to Broekelschen's symptoms before applying the *Althen* test, is not supported by statute, caselaw, or logic, and its effect was to impermissibly heighten Broekelschen's burden. Contrary to the majority, the language of the Vaccine Act does not support the special master's approach by narrowly limiting its application to known injuries. Instead, it broadly defines a "vaccine-related injury or death" as "an illness, injury, condition, or death." 42 U.S.C. § 300aa-33(5). Petitions for compensation must demonstrate that the claimant sustained "any illness, disability, injury, or condition" caused by a vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Therefore, even in the absence of a definitively diagnosed injury, claimants such as Broekelschen 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.

The majority emphasizes that the parties' dispute as to the diagnosis makes this case unique and therefore justifies the initial step of determining a diagnosis before applying the *Althen* test. However, every case is unique and nothing about the facts in this case supports the majority's unwarranted departure from our precedent. As the special master recognized, the range of symptoms Broekelschen experienced could be explained by either diagnosis, and "determining which condition affects Dr. Broekelschen is one step in determining the cause for Dr. Broekelschen's condition." *Broekelschen v. Sec'y of Health & Human Servs.*, No. 07-137V, 2009 WL 440624 at *4 (Fed. Cl. Sp. Mstr. Feb. 4, 2009). Therefore, the analysis of the diagnosis should have been part of the first prong of the *Althen* test, which requires a "medical theory causally connecting the vaccination and the injury." 418 F.3d at 1278. The medical theory proposed by Broekelschen was that his symptoms were caused by the vaccine through the pathway of TM; his theory of causation is therefore inextricably linked to the diagnosis. The special master should have first determined whether Broekelschen demonstrated that it was more likely than not that his symptoms resulted from TM caused by an immune response to the vaccine. Only then should the special master have considered whether the government could show by preponderant evidence that other factors caused the injury, *i.e.*, that Broekelschen's symptoms were caused by anterior spinal artery syndrome unrelated to the influenza vaccine.

The majority cites to *Doe v. Secretary of Health & Human Services*, 601 F.3d 1349 (Fed. Cir. 2010), in support of the proposition that the special master appropriately considered the government's alternative theory of diagnosis prior to applying the *Althen* test. That reliance is misplaced. In *Doe* we affirmed the decision of a special

master who allowed the government to present evidence that the cause of death was sudden infant death syndrome ("SIDS"), rather than a vaccine, to rebut the claimants' theory of causation. *Id.* The claimants in that case, however, relied on the elimination of SIDS as a potential cause of death to establish their prima facie case, and the special master considered the evidence relating to SIDS only "in evaluating whether Doe's proposed sequence of cause and effect was plausible." *Id.* at 1353. Here the special master did not limit his evaluation of the government's theory of diagnosis to determining whether it undercut the evidence Broekelschen presented to establish a prima facie case. Instead, he used diagnosis as a prerequisite step, denying Broekelschen the opportunity of even attempting to establish a prima facie case. In any event, *Doe* does not overrule our precedent that a vaccine claimant is not required to eliminate alternative causes of injury in establishing a prima facie case. *Id.* at 1358 ("A petitioner's failure to meet his burden of proof as to the cause of an injury or condition is different from a requirement that he affirmatively disprove an alternative cause."); *see also de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) ("So long as the petitioner has satisfied all three prongs of the *Althen* test, she bears no burden to rule out possible alternative causes."); *Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1150 (Fed. Cir. 2007) ("[T]he Vaccine Act does not require the petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case.").

The special master also erred in basing his decision, in part, on his view that the government's expert witness was more credible than Broekelschen's. While the special master praised the experience and demeanor of both experts, he stated that he gave more weight to the gov-

ernment's expert because he found the government's expert to have a more persuasive demeanor and a more impressive background. *Broekelschen*, 2009 WL 440624 at *13, *18. This analysis is inappropriate for two reasons. First, the *Althen* test does not support a head-to-head comparison between dueling experts, but shifts the burden to the government only after the claimant has made a prima facie case for entitlement. The special master therefore should not have analyzed which expert was more persuasive, but whether Broekelschen's expert, along with the record evidence, showed that it was more likely than not that Broekelschen's condition was caused by TM resulting from the vaccination. If so, the special master's analysis should have continued to determine whether the government's expert showed that it was more likely than not that the condition was caused by factors unrelated to the vaccine.

Second, while the credibility determinations of special masters are owed deference, we have held that credibility determinations are appropriately used to assess the candor of a fact witness, "not to evaluate whether an expert witness' medical theory is supported by the weight of epidemiological evidence." *Andreu*, 569 F.3d at 1379. In other words, credibility determinations can be used to determine if an expert is reliable, but weighing the persuasiveness of the competing medical theories is a separate analysis. Once the special master determined both experts were highly qualified and reliable, there was no reason for him to give any additional weight to the background or demeanor of the government's expert. The focus should have been solely on the "relative persuasiveness of the competing medical theories of the case." *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000).

Our decision in *Moberly v. Secretary of Health & Human Services*, 592 F.3d 1315 (Fed. Cir. 2010), in which we affirmed the denial of a claim where the special master discredited the testimony of the claimant's expert, does not support the approach taken by the special master in this case. In *Moberly*, *none* of the treating physicians expressed the view that the claimant's injury was caused by the vaccination she received. Instead, the record evidence supporting the opinion of the claimant's expert "amount[ed] at most to a showing of temporal association between a vaccination and a seizure, together with the absence of any other identified cause for the . . . injury." *Id.* at 1323. In this case, contemporaneous records created by treating physicians support Broekelschen's theory. Furthermore, the special master and both experts noted that there is evidence in the record to support and refute each of the two potential diagnoses. While nothing in the record conclusively proves that Broekelschen's symptoms were caused by TM resulting from the vaccination, conclusive proof is not required. *Knudsen v. Sec'y of Heath & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994) ("The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain."); *see also Althen*, 418 F.3d at 1280 ("[T]he purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.").

The majority holds that the special master's error in weighing the expert witnesses' credibility is harmless. This is mere speculation. It is not clear that the outcome of the case would have been the same if the special master had appropriately weighed the expert witness testimony, particularly if he had done so within the prevailing

framework of *Althen* by allowing Broekelschen to attempt to make a prima facie showing that his symptoms resulted from vaccine-induced TM. I would therefore remand to allow the special master to properly apply the test laid out in *Althen* to Broekelschen's claim and appropriately weigh the expert witness testimony.