United States Court of Appeals for the Federal Circuit

MAREK MILIK, JOLANTA MILIK, LEGAL GUARDIANS AND PARENTS OF A.M.,
Petitioners-Appellants

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,
Respondent-Appellee

2015-5109

Appeal from the United States Court of Federal Claims in No. 1:01-vv-00064-PEC, Chief Judge Patricia E. Campbell-Smith.

Decided: May 20, 2016

ROBERT JOEL KRAKOW, Law Office of Robert J. Krakow, New York, NY, argued for petitioners-appellants.

ROBERT PAUL COLEMAN III, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, argued for respondent-appellee. Also represented by GABRIELLE M. FIELDING, VINCENT J. MATANOSKI, RUPA BHATTACHARYYA, BENJAMIN C. MIZER, LISA WATTS.

Before O'MALLEY, WALLACH, and HUGHES, *Circuit Judges.*

O'MALLEY, *Circuit Judge.*

Petitioners Marek and Jolanta Milik (collectively, "the Miliks"), on behalf of their son, A.M., appeal the final judgment of the United States Court of Federal Claims affirming a special master's decision denying compensation under the National Childhood Vaccine Injury Act of 1986 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34) ("the Vaccine Act"). *Milik v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 68 (2015). The special master found that the Miliks failed to prove by a preponderance of the evidence that a measles, mumps, and rubella ("MMR") vaccine caused A.M. to develop a severe neurological condition, involving developmental delay, spastic diplegia, and motor difficulties. *Milik v. Sec'y of Health & Human Servs.*, No. 01-64V, 2014 WL 6488735 (Fed. Cl. Spec. Mstr. Oct. 29, 2014) ("*Special Master Decision*"). 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.

I. BACKGROUND

A. Factual Background

The relevant facts are primarily those found by the special master in his detailed October 29, 2014 decision. A.M. was born on December 5, 1993, and was raised in a predominately Polish-speaking household. *Special Master Decision*, 2014 WL 6488735, at *3. At A.M.'s fifteen-month routine examination, the pediatrician noted that A.M. was "doing well" and was a "well child." *Id.* In December 1995, when A.M. was two years old, his pediatrician noted that "A.M. responded to sound, used 4 to 10 words ('mama' and 'dada' were noted specifically), walked up stairs, and walked independently." *Id.* During subsequent visits in 1996, A.M.'s new pediatrician, Dr. Mitchell

Weiler, noted that A.M. could speak several words in English. *Id.*

On January 29, 1998, when A.M. was four years and one month old, he received his second MMR vaccination. *Id.* Eleven days later, A.M. returned to Dr. Weiler's office complaining of a sore throat. "Dr. Weiler diagnosed A.M. with pharyngitis (throat swelling) and otitis media (ear infection), and treated him with an antibiotic." *Id.* Dr. Weiler rechecked A.M.'s ears on February 23, 1998. His notes from that appointment stated that A.M. had a "Trauma. Slipped/Fell" and that he had a limp, but he was seen by a podiatrist and the x-rays were negative. *Id.* at *4.

On March 2, 1998, A.M. saw Dr. Joseph Maytal, a pediatric neurologist, for complaints of limping. *Id.* Dr. Maytal made several observations during the examination, including that A.M. did not know his last name, he only spoke single words in English, and his parents were unsure if he could use plurals. *Id.* Dr. Maytal gave A.M. a provisional diagnosis of "Ataxia/Unsteadiness and Developmental Delay." *Id.* He also opined that A.M. had two issues:

> One is the *longstanding* issue of this youngster who is globally delayed mostly in the language/communicative skills but also in his fine motor and possibly in his gross motor skills . . . . The second issue is his acute symptoms of "limping." As a precaution I would like to consider the reason for his limping . . . with an MRI.

Id. (emphasis added). According to Dr. Maytal, the MRI showed "diffuse white matter demyelination which is consistent with demyelinating process most likely some form of leukodystrophy." *Id.*

In July 1998, A.M. saw Dr. Krystyna Wisniewski, a pediatric neurologist who was part of an interdisciplinary

team of specialists at the George A. Jervis Clinic, New York State Institute for Basic Research in Developmental Disabilities ("IBR"). Dr. Wisniewski noted that A.M.'s "cognitive function seems to be appropriate for his chronological age. He knows colors, numbers, and follows three step commands. His visual perception seems to be impaired." *Milik*, 121 Fed. Cl. at 75. Dr. Wisniewski diagnosed A.M. with "spastic diplegia, more right than left." *Special Master Decision*, 2014 WL 6488735, at *4.

Dr. Maria Malinowska, a bilingual psychologist, evaluated A.M. in September 1998. *Id.* at *5. She determined that, at four years and nine months of age, A.M. had "motor and speech/language difficulties as well as attentional problems." *Id.* Dr. Malinowska concluded that these difficulties "are most likely due to an organic brain dysfunction interfere [sic] with his intellectual and adaptive functioning." *Id.* A.M. also saw Dr. Ricardo Madrid for a neuromuscular evaluation. Dr. Madrid opined that A.M.'s condition was "suggestive but not diagnostic of post infectious or post vaccination acute encephalomyelitis." *Id.* But because A.M. did not experience seizure, fever, and altered mental state—symptoms that are typically expected with a vaccine complication—Dr. Madrid doubted that A.M.'s disorder arose from a "neurological complication associated with MMR vaccination." *Id.*

The medical records provide little information regarding A.M.'s care after 1998. A group of physicians reevaluated A.M.'s condition beginning in 2011. At that time, A.M. was wheelchair-bound and unable to care for himself. In March 2012, when he was eighteen years old, A.M. saw a specialist in medical genetics who opined that "[t]he finding of apparently normal development followed by a sudden loss of abilities following an insult with severe demyelination is suggestive of vanishing white matter disease. This often presents during childhood with ataxia following infection or fright." *Id.* at *6.

B. Procedural History

The Miliks filed a petition for compensation on January 31, 2001, on behalf of A.M., alleging that he "suffered injuries including spastic diplegia (paraplegia) causing [him] to walk with a permanent and debilitating limp, severe gross and fine motor difficulties as well as difficulties learning, all of which were 'caused-in-fact by administration of the MMR vaccination.'" *Milik*, 121 Fed. Cl. at 70-71. The Secretary filed a report opposing the petition for compensation. At the Miliks' request, proceedings were delayed for several years to allow time to obtain counsel and file expert reports.

The Miliks filed two expert reports, the first of which was a one-page letter from Dr. Logush, a pediatric neurologist at the IBR where A.M. was treated. In that letter, Dr. Logush stated that A.M.'s history was "suggestive but not diagnostic of post infectious or post vaccine, immunologically induced acute disseminated encephalitis vs. encephalomyelitis." *Special Master Decision*, 2014 WL 6488735, at *25. Dr. Logush offered the same conclusion after he conducted a follow-up examination of A.M. in February 2011. *Milik*, 121 Fed. Cl. at 77. Although Dr. Logush participated in a telephone conference with the special master where he stated that it was "very probable" that the MMR vaccine caused A.M.'s injury, he did not ultimately testify as the Miliks' expert. *Special Master Decision*, 2014 WL 6488735, at *25.

The Miliks' second expert report, filed in November 2011, was from Dr. Nizar Souayah, the neurologist who testified as their expert witness. Dr. Souayah is board-certified in neurology, electrodiagnostic medicine, and neuromuscular medicine. *Id.* at *8. Dr. Souayah opined that A.M.'s condition was "consistent with an extensive white matter disease that started approximately 3 weeks after MMR vaccination" and that "A.M. suffered an 'encephalopathy or encephalitis,' caused by the MMR vac-

cine, at that time." *Id.* at *9. In both his written report and his testimony, Dr. Souayah opined that the MMR vaccine caused A.M.'s injury because: (1) A.M. experienced normal health and development before the vaccine; (2) 22 days after receiving the MMR vaccination, A.M. developed a limp; (3) no other cause for A.M.'s injury was identified, despite extensive testing; and (4) the MMR vaccine has been suspected of causing central nervous system damage. *Id.*

In response, the government filed two expert reports from Dr. Michael Kohrman, who is "board-certified in neurology and psychiatry, with a special competency in child neurology and sleep medicine, and also board-certified in pediatrics." *Id.* Dr. Kohrman opined that A.M. had a *pre-existing* global developmental delay, and that his condition is "likely to be a result of a 'vanishing white matter' disease, such as an unidentified form of leukodystrophy, that began around two years of age when the first signs of developmental delay appeared." *Id.* In the alternative, Dr. Kohrman submitted that, even if A.M.'s symptoms did not appear until after the MMR vaccination, "the cause would still more likely have been an infection from which A.M. was suffering at the time, rather than his vaccination." *Id.*

In March 2013, the special master held an evidentiary hearing and heard testimony from Dr. Souayah and Dr. Kohrman. Both parties filed post-hearing briefs. A year after the hearing, the Miliks filed a motion for consideration of new medical evidence, seeking to introduce a letter from Dr. Maytal, A.M.'s pediatric neurologist. *Id.* at *7. In that letter, Dr. Maytal sought to clarify that his use of the term "longstanding" in reference to A.M.'s global delay should be interpreted as "a condition existing prior to examination," and that his group was "unable to determine the time length of symptoms." *Id.* at *12. The special master admitted the letter over the government's objection.

On October 29, 2014, the special master issued a detailed decision denying the Miliks' petition for compensation. At the outset, the special master noted that, although both experts agreed that A.M. suffers from a severe developmental disorder, they disagreed as to the cause. Weighing the expert testimony, the special master found Dr. Kohrman—the government's expert—more persuasive, and credited his opinion that the onset of A.M.'s developmental delay preceded the MMR vaccination. *Id.* at *10.

Recognizing that the parties presented A.M.'s condition as a single global entity involving *both* mental delay and physical problems, and that the Miliks never argued that they were distinct injuries, the special master found no evidentiary basis to conclude that part of A.M.'s disability was vaccine-caused. *Id.* at *27.[1] Accordingly, the special master concluded that the Miliks had not shown by preponderant evidence that the MMR vaccination caused A.M.'s disorder. *Id.* at *27-28 (citing *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). In the alternative, the special master found that: (1) A.M. did not suffer an encephalopathy or encephalitis; (2) even if he did, the more likely cause was an infection A.M. had at the time; and (3) the onset of A.M.'s limping was outside the medically accepted timeframe. *Id.* at *17-20.

The Miliks sought review of the special master's decision in the Court of Federal Claims, asserting three primary arguments. First, they argued that the Court of

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[1] During oral argument before this court, counsel for the Miliks reiterated that they did not attempt to separate A.M.'s condition into two distinct issues. Oral Argument at 19:17-20:08, *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-5109.mp3.

Federal Claims is constitutionally required to conduct a de novo review of the special master's decision. *Milik*, 121 Fed. Cl. at 72 n.11 (citing *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011)). Second, the Miliks objected to the special master's onset finding, and his determination that Dr. Kohrman was more credible and persuasive than Dr. Souayah. *Id.* at 72. Finally, the Miliks objected to the special master's alternative findings.

In a decision dated April 29, 2015, the Court of Federal Claims sustained the special master's decision. The court began by dismissing the Miliks' constitutional argument regarding the applicable standard of review in a footnote, agreeing with the government that the Vaccine Act "does not bar a petitioner from later filing a claim in an Article III federal court, and that petitioners' reliance on *Bruesewitz* is misplaced." *Id.* at 72 n.11.

The court then considered the Miliks' objections to the special master's onset finding that A.M.'s global developmental delay preceded his MMR vaccination. Although the court found that some of Dr. Kohrman's inferences based on A.M.'s well-child examinations were not well-supported, it concluded that the special master's decision "was not based solely, or even largely, on those records." *Id.* at 86. Instead, the special master based his decision on a number of other records, including: (1) Dr. Maytal's March 1998 diagnosis of longstanding global delay; (2) Dr. Malinowska's September 1998 diagnosis of delay in communication, daily living skills, and motor skills; (3) A.M.'s parents' repeated reports that he suffered no cognitive regression; and (4) Dr. Kohrman's interpretation of two MRI studies of A.M.'s brain taken in 1998. *Id.* Because the special master's onset decision was based on reliable evidence in the record, the court concluded that it was not arbitrary or capricious. And, because the court sustained that decision, it found it unnecessary to consider the Miliks' objection to the special master's alternative findings. *Id.* at 87.

The Miliks timely appealed to this court, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3) and 42 U.S.C. § 300aa-12(f).

II. DISCUSSION

On appeal, the Miliks argue that: (1) the Vaccine Act, and its attendant arbitrary and capricious standard of review, is unconstitutional because it deprives petitioners of their right to de novo review in an Article III court; and (2) even if the standard of review is constitutional, the special master's decision denying compensation is arbitrary and capricious because it is unsupported in the record. We address each argument in turn.

A. Jurisdiction and Standard of Review

"Childhood vaccinations, though an important part of the public health program, are not without risk." *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1306 (Fed. Cir. 1999). Recognizing that vaccines can cause serious adverse side effects in rare circumstances, "Congress became concerned that tort liability and related costs might drive up the prices of vaccines and discourage vaccine manufacturers from staying in this market, and that normal tort litigation might leave many sufferers of vaccine-caused injuries uncompensated." *Id.* at 1307 (citing H.R. Rep. No. 99-908, at 1, 4, 6-7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6287, 6345, 6347-48).

Accordingly, Congress enacted the Vaccine Act in 1986 to increase the safety and availability of vaccines. *Id.* at 1307. The Vaccine Act created the National Vaccine Injury Compensation Program ("the Program"), through which claimants can petition for compensation for vaccine-related injury or death. *See* 42 U.S.C. § 300aa-10(a). In doing so, the Act established a no-fault compensation program "designed to work faster and with greater ease than the civil tort system." *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995). The Act requires claim-

ants to seek relief through the Program before filing a civil action in a state or federal court against a vaccine administrator or manufacturer for damages in an amount greater than $1,000. 42 U.S.C. § 300aa-11(a)(2)(A).

As originally enacted, the Vaccine Act provided the "district courts of the United States" jurisdiction to determine if a petitioner was entitled to compensation under the Program. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 2112(a), 100 Stat. 3743, 3761. The district court would designate a special master to prepare proposed findings of fact and conclusions of law. *Id.* at § 2112(c), 100 Stat. at 3761-62. The Act provided that, "upon objection . . . to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings." *Id.* at § 2112(d)(1), 100 Stat. at 3762.

The Vaccine Compensation Amendments of 1987 transferred jurisdiction from "district courts of the United States" to "the United States Claims Court." *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4307, 101 Stat. 1330, 1330-224 to 1330-225 (amending 42 U.S.C. § 300aa-11).[2] Congress subsequently amended the Act to establish, within the United States Claims Court, an office of special masters to review compensation claims. *See* Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6601(e), 103 Stat. 2106,

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[2] Congress later replaced the references to the "United States Claims Court" with the "United States Court of Federal Claims." *See* Court of Federal Claims Technical and Procedural Improvements Act of 1992, Pub. L. No. 102-572, § 902, 106 Stat. 4506, 4516.

2286-89 (amending 42 U.S.C. § 300aa-12). At the same time, Congress changed the standard of review. Rather than de novo review, the amendment provided that the Claims Court "shall have jurisdiction to . . . set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusion of law." *Id.* at § 6601(h)(2)(B), 103 Stat. at 2289-90 (codified at 42 U.S.C. § 300aa-12(e)(2)(B)). By statute, the Court of Federal Claims' judgment may be reviewed in this court. 42 U.S.C. § 300aa-12(f).

We review an appeal from the Court of Federal Claims in a Vaccine Act case de novo, applying the same standard of review that court applied in reviewing the special master's decision. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (citing *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009)). Although we review legal determinations without deference, we review the special master's factual findings under the arbitrary and capricious standard. *Griglock v. Sec'y of Health & Human Servs.*, 687 F.3d 1371, 1374 (Fed. Cir. 2012); *see Hines v. Sec. of Health & Human Servs.*, 940 F.2d 1518, 1524 (Fed. Cir. 1991) ("In effect, then, we review the underlying decision of the special master under the arbitrary and capricious standard of § 300aa-12(e)(2)(B).").

The arbitrary and capricious standard is "difficult for an appellant to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact." *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000). If the special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision," then reversible error is "extremely difficult to demonstrate." *Hines*, 940 F.2d at 1528. As this court has recognized:

> Congress assigned to a group of specialists, the Special Masters within the Court of Federal Claims, the unenviable job of sorting through these painful cases and, based upon their accumulated expertise in the field, judging the merits of the individual claims. The statute makes clear that, on review, the Court of Federal Claims is not to second guess the Special Masters fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on our review of the judgment of the Court of Federal Claims, we remain equally deferential. That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.

Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (internal citations omitted). Accordingly, we "do not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses – these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing *Broekelschen*, 618 F.3d at 1349). Rather, as long as the special master's "conclusion [is] based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious." *Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (citation omitted).

On appeal, the Miliks argue that the Vaccine Act unconstitutionally denies them access to de novo review in an Article III court. Specifically, they argue that, by limiting a vaccine injury claimant to filing a claim against the Secretary in an Article I court, "the Vaccine Act has deprived petitioners of the rights granted in Article III of the United States Constitution and the common law

protections afforded in state courts for tortious injuries against the manufacturers of vaccines." Pet'rs Br. 14-15. The Miliks point to two recent Supreme Court decisions which they argue, when taken together, support their argument that the Vaccine Act is unconstitutional: *Bruesewitz v. Wyeth LLC*, 562 U.S. 223 (2011), and *Stern v. Marshall*, 564 U.S. 462 (2011).

In *Bruesewitz*, the Court held that the Vaccine Act "pre-empts all design-defect claims against vaccine manufacturers brought by plaintiffs who seek compensation for injury or death caused by vaccine side effects." 562 U.S. at 243. There, the Court considered 42 U.S.C. § 300aa-22(b)(1), which provides that:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

Given the statutory text, the Court concluded that, as long as "there was proper manufacture and warning, any remaining side effects, including those resulting from design defects, are deemed to have been unavoidable. State-law design-defect claims are therefore preempted." *Id*. at 231-32.

The Miliks also cite the Supreme Court's decision in *Stern*, which reiterated that:

> Congress may not "withdraw from judicial cognizance any matter which, from its nature, is the subject of a suit at the common law, or in equity, or admiralty." *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. 272 (1856). When a suit is made of "the stuff of the traditional actions

> at common law tried by the courts at Westminster in 1789," . . . and is brought within the bounds of federal jurisdiction, the responsibility for deciding that suit rests with Article III judges in Article III courts. The Constitution assigns that job—resolution of "the mundane as well as the glamorous, matters of common law and statute as well as constitutional law, issues of fact as well as issues of law"—to the Judiciary.

564 U.S. at 484 (citation omitted). Applying these principles in *Stern*, the Court held that an Article I bankruptcy court "lacked the constitutional authority to enter a final judgment on a state law counterclaim that is not resolved in the process of ruling on a creditor's proof of claim." *Id.* at 503. In reaching this conclusion, the Court noted that it was not dealing with "a situation in which Congress devised an 'expert and inexpensive method for dealing with a class of questions of fact which are particularly suited to examination and determination by an administrative agency specially assigned to that task.'" *Id.* at 494 (citation omitted). Instead, the "'experts' in the federal system at resolving common law counterclaims such as Vickie's [tortious interference counterclaim] are the Article III courts, and it is with those courts that her claim must stay." *Id.*[3]

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[3] *Stern* was recently narrowed in *Wellness International Network v. Sharif*, 135 S. Ct. 1932 (2015). There, the Court made clear that "Article III is not violated when the parties knowingly and voluntarily consent to adjudication by a bankruptcy judge." *Id.* at 1939. The Court explained that "allowing Article I adjudicators to decide claims submitted to them by consent does not offend the separation of powers so long as Article III courts retain supervisory authority over the process." *Id.* at 1944.

The Miliks' briefing on *Stern* is sparse, and the government's response does not address it. At oral argument, counsel for the Miliks clarified their position as follows:

> Under the original understanding of the Act, there was an opportunity for a petitioner to reject the judgment in the Vaccine court or elect to proceed in a state or federal court under common law or under state statutes. That is now gone. We submit that a litigant bringing these kinds of claims is entitled to de novo review in an Article III court, as it traditionally would be available.

Oral Argument at 3:02-3:37, *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-5109.mp3. The Miliks suggest that, in light of *Stern*—which says that, unless certain exceptions apply, Congress cannot take away access to Article III courts for resolution of common law claims—the Supreme Court's decision in *Bruesewitz* rendered the Vaccine Act unconstitutional because it does just that. We disagree.

The separation of powers concerns at play in *Stern* are not implicated by *Bruesewitz*. In the Vaccine context, the only questions the special master addresses are those related to the fact of injury and causation. No liability issues are determined by the special master; it is a no fault statute that assumes the right to recovery whenever injury and causation are established. The "design defect" question is never addressed by the Article I court or its special master program.

The issues that *are* addressed are not barred from subsequent Article III review. While the legal theories under which questions of injury and causation may be reconsidered by the Article III court may be narrowed by *Bruesewitz's* reading of the Vaccine Act, those questions nonetheless can be revisited. Indeed, the Miliks could revisit the very issues decided by the special master in the

context of a manufacturing defect claim, breach of express or implied warranty claims, or even a contract claim if the predicate for such claims exists. Thus, even if *Stern* were applicable to these facts, its limitations would not be violated.

More importantly, however, is the fact that *Stern* is *not* applicable here. The only constitutional question *Bruesewitz* implicates is whether Congress may preempt a cause of action altogether, such that no court may decide the claim. There is no doubt Congress has the authority under the Supremacy Clause to preempt state law causes of action which conflict with the federal standards and policies set forth in a duly authorized federal statute. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001) ("State action may be foreclosed by express language in a congressional enactment, by implication from the depth and breadth of a congressional scheme that occupies the legislative field, or by implication because of a conflict with a congressional enactment." (internal citations omitted)). That is precisely what the Court in *Bruesewitz* said Congress did when it passed the Vaccine Act. *See Bruesewitz*, 562 U.S. at 231-33. We have no authority to disagree with that conclusion, and do not believe *Stern* provides a vehicle for doing so. *Stern* simply does not address the preemption of state law claims; it only addresses who may decide claims that are not otherwise preempted.

Because the Court's decision in *Stern* does not apply in these circumstances, and because the Court's decision in *Bruesewitz* has no bearing on the applicable standard of review, we continue to review the special master's findings of fact under the deferential arbitrary and capricious standard.

B. The Special Master's Decision Was Neither Arbitrary Nor Capricious

A petitioner seeking compensation under the Vaccine Act must show, by a preponderance of the evidence, "that the injury or death at issue was caused by a vaccine." *Broekelschen*, 618 F.3d at 1341 (citing 42 U.S.C. §§ 300aa-11(c)(1), -13(a)(1)). A petitioner can establish causation in one of two ways. *Id.* If the petitioner shows that he or she received a vaccination listed on the Vaccine Injury Table, 42 U.S.C. § 300aa-14, and suffered an injury listed on that table within a statutorily prescribed time period, then the Act presumes the vaccination caused the injury. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009). Where, as here, the injury is not on the Vaccine Injury Table, the petitioner may seek compensation by proving causation-in-fact. *Id.*

To prove causation, a petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Specifically, the petitioner must show the following by a preponderance of the evidence: (1) a medical theory causally connecting the vaccination to the injury; (2) a logical sequence of cause and effect demonstrating that the vaccination caused the injury; and (3) a proximate temporal relationship between the vaccine and the injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). If the petitioner satisfies this burden, he 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." *Broekelschen*, 618 F.3d at 1341 (citing *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1351 (Fed. Cir. 2010)).

The special master found that the Miliks met their burden of establishing the first prong of the *Althen* test,

but failed to meet prongs two and three. Indeed, as to the first prong, both parties' experts agreed that the MMR vaccination is *capable* of causing an encephalitis or encephalopathy. *Special Master Decision*, 2014 WL 6488735, at *28. As to prong two, the special master found that the Miliks failed to show that the MMR vaccine caused A.M.'s condition because the record evidence revealed that A.M. had a preexisting developmental delay. *Id.*[4] Although the special master deemed it unnecessary to address the third *Althen* prong, given his finding that the Miliks did not satisfy the second, he nonetheless found that A.M.'s condition did not fit the timeframe discussed in the medical literature of record, thus precluding a finding of a proximate temporal relationship between the vaccine and injury. *Id.*

On appeal, the Miliks allege that there was "no credible evidence supporting the special master's finding that A.M. had a developmental disorder preceding the administration of the MMR vaccination." Pet'rs Br. 11. Specifically, they argue that the special master erred in: (1) determining that the onset of A.M.'s condition predated the vaccine; (2) rejecting Dr. Maytal's clarification of the term "longstanding"; and (3) crediting Dr. Kohrman's opinion over that of Dr. Souayah. As to the alternative findings, the Miliks contend that the special master erred in finding that they failed to show a medically appropriate temporal relationship between A.M.'s condition and the MMR vaccine.

The Miliks' essentially ask this court to reweigh the factual evidence and assess the credibility of the witnesses. As an appellate tribunal, we can do neither. *See*

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[4] The special master clarified that the Miliks "failed to show that A.M.'s condition was either initially caused by his vaccinations, or was aggravated in any way by his vaccinations." *Id.* at *28 n.31.

Porter, 663 F.3d at 1249. And, as explained below, because the special master's onset decision was based on reliable evidence of record, it was neither arbitrary nor capricious.

First, the Miliks argue that the contemporaneous medical records reveal that A.M.'s pre-vaccination development was normal, and that none of his treating physicians noted any developmental delay. The Miliks further note that the Court of Federal Claims found "multiple instances where the record *failed to support* the special master's findings" with respect to A.M.'s pre-vaccination development. Pet'rs Br. 17.

While it is true that the court found some of Dr. Kohrman's inferences unsupported, the special master considered all of the evidence of record and relied substantially on one of the first contemporaneous medical records created: Dr. Maytal's diagnosis that A.M. suffered from "longstanding" global developmental delay. *See Special Master Decision*, 2014 WL 6488735, at *10. The special master also relied on records from A.M.'s bilingual psychologist—Dr. Malinowska—showing that, at age four years and nine months, A.M. was delayed in his communication, daily living, and motor skills. *Id.* at *14. These reports, coupled with the Miliks' own representation that A.M. did not experience cognitive regression post-vaccination, supported the inference that A.M.'s developmental delay must have preceded the vaccination. *Id.*

The special master further considered two of A.M.'s post-vaccination MRI studies conducted in 1998, both of which showed no interval changes. *Id.* at *15. Dr. Kohrman opined that those studies were "consistent with a demyelinating or dysmyelinating process that produced *longstanding* developmental delay dating back to his examination at the age of two years." *Id.* In light of the foregoing, we agree with the Court of Federal Claims that "the special master based his finding that the onset of

A.M.'s global developmental delay preceded his MMR vaccination on reliable evidence in the record." *Milik*, 121 Fed. Cl. at 86.

Next, the Miliks argue that the special master unfairly rejected as "litigation driven" Dr. Maytal's letter clarifying his use of the term "longstanding." As noted, in March 1998, Dr. Maytal examined A.M. and identified two issues: "longstanding" global delay and "acute" symptoms of limping. Roughly sixteen years later, Dr. Maytal sent a letter stating that the "term 'longstanding' should be interpreted as 'a condition existing prior to examination.' We are unable to determine the time length of symptoms." *Special Master Decision*, 2014 WL 6488735, at *12.

Recognizing that Dr. Maytal's letter was "not contemporaneous to the events to which it sp[oke]," and was "outside the context of diagnosis and treatment," the special master found that it was "entitled to less deference." *Id*. at *12 n.14. Although the special master classified Dr. Maytal's letter as "litigation driven," he did not reject it for that reason. Instead, the special master "found that the meaning of longstanding urged by petitioners simply did not make sense within the context of Dr. Maytal's original diagnosis." *Milik*, 121 Fed. Cl. at 82.

The special master began by looking to the dictionary definition of "longstanding," which is "of long duration." *Special Master Decision*, 2014 WL 6488735, at *12 n.15. He then noted that Dr. Maytal performed his initial examination only one month after A.M. received the MMR vaccination. The special master found that the "ordinary use of the term 'longstanding' would indicate that the delay had lasted substantially longer than one month." *Id*. at *12. Next, the special master found it significant that Dr. Maytal's original report contrasted A.M.'s "longstanding" delay with his "acute" onset of limping, which began ten days prior to the examination. To accept

Dr. Maytal's clarification of "longstanding" to mean "a condition existing prior to the examination," would "erase the distinction he originally drew between the 'longstanding' global delay and the 'acute' symptom of limping, and would make the original record *incoherent* as written." *Id.* On this record, we conclude that the special master reasonably chose to credit the plain meaning of "longstanding" over Dr. Maytal's belated clarification.

Finally, the Miliks argue that the special master erred in finding Dr. Kohrman, the government's expert, more persuasive than Dr. Souayah. It is well established that "[f]inders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1326 (Fed. Cir. 2010). We have recognized that "special masters have that responsibility in Vaccine Act cases." *Id.* at 1325. We have further recognized that a "special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories," and that the special master's credibility findings "'are virtually unchallengeable on appeal.'" *Broekelschen*, 618 F.3d at 1347 (quoting *Lampe*, 219 F.3d at 1361).

The record reveals that the special master considered the conflicting testimony from the parties' experts and reasonably concluded that Dr. Kohrman's opinion was entitled to more weight. To begin, the special master found that Dr. Souayah's testimony was based on a "flawed assumption as to the time of onset of A.M.'s neurological dysfunction." *Special Master Decision*, 2014 WL 6488735, at *16. The special master also found that Dr. Kohrman was more qualified to address the issues in this case, given that he is a pediatric neurologist who sees children with neurological problems on a regular basis. In contrast, Dr. Souayah generally treats adults and "has

not diagnosed developmental delay in a child since his residency in 2002." *Id.*

The special master further found Dr. Kohrman more persuasive because his testimony evinced a more detailed understanding of the Denver Developmental Screening Test ("the Denver test"), which Dr. Maytal applied in his examination of A.M. *Id.* at *11-12. Dr. Kohrman explained that failing one of the Denver test's language domains is cause for concern, and that "Dr. Maytal noted that A.M. failed *three* language domains—A.M. could not use plurals, could not use his last name, and failed to comprehend cold." *Id.* at *12. While Dr. Kohrman analyzed A.M.'s scoring under the Denver criteria, Dr. Souayah "did not touch on any of the specifics of the Denver test." *Id.* We find nothing arbitrary or capricious about the special master's determination that Dr. Kohrman's testimony was more persuasive than that of Dr. Souayah. *See Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1379-80 (Fed. Cir. 2012) (finding "nothing arbitrary or capricious" about the special master's decision to credit the government expert's testimony regarding the onset of injury).

This case, like so many in the Vaccine Act context, turns on its facts. While we agree with the Court of Federal Claims that some of the inferences Dr. Kohrman drew from A.M.'s pre-vaccination records were unsupported, we also agree that the special master's decision "was not based solely, or even largely, on those records." *Milik*, 121 Fed. Cl. at 86. We conclude that the special master thoroughly reviewed all of the relevant evidence, including the expert witnesses' testimonies and reports, and that the record supports his finding that A.M.'s developmental delay predated the MMR vaccination. We therefore cannot say that the special master's onset decision was arbitrary or capricious. Because the Miliks failed to show that the MMR vaccination caused A.M.'s injury, they did not meet their burden under the second

Althen prong, and the special master correctly denied the petition for compensation. Given this conclusion, we need not address the special master's alternative findings.

III. CONCLUSION

While we certainly sympathize with the Milik family, we conclude that the special master's decision was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). For the foregoing reasons, and because we find the Miliks' remaining arguments unpersuasive, we affirm the judgment of the Court of Federal Claims.

AFFIRMED

COSTS

No costs.