2015-5043

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

FRANCIA HIRMIZ, PETER HIRMIZ, as best friends of their daughter, J.H.,

Petitioners-Appellants,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

Appeal from a judgment of the United States Court of Federal Claims
in Case No. 06-VV-371, JUDGE CHARLES F. LETTOW

BRIEF OF RESPONDENT-APPELLEE SECRETARY OF HEALTH AND HUMAN SERVICES

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I. STATEMENT OF RELATED CASES

No appeal of this case has been before this or any other appellate court. To the knowledge of respondent-appellee, the Secretary of Health and Human Services ("the Secretary"), there is no same or similar Vaccine Act case pending before the Supreme Court, this Court, or any other Circuit Court of Appeals.

II. COUNTER-STATEMENT OF THE ISSUES

Whether the special master correctly determined that petitioners-appellants, Francia and Peter Hirmiz (hereinafter "petitioners") failed to prove by a preponderance of the evidence that vaccinations administered to their minor daughter, J.H., caused J.H.'s neurological degeneration.

III. STATEMENT OF THE CASE

A. Statutory Scheme: National Childhood Vaccine Injury Act.

In 1986, Congress passed the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act" or "Act"), as amended, establishing a program administered by the Secretary of Health and Human Services to increase the safety and availability of vaccines. *See* 42 U.S.C. § 300aa-1; *Terran v. HHS*, 195 F.3d 1302, 1307 (Fed. Cir. 1999). The Vaccine Act created the National Vaccine Injury Compensation Program, through which claimants could petition to receive compensation for vaccine-related injuries or death. *See* 42 U.S.C. § 300aa-10(a).

The Vaccine Act established an Office of Special Masters within the United States Court of Federal Claims to issue decisions on petitions for compensation (42 U.S.C. §§ 300aa-12(c)(1), 300aa-12(d)(3)(A)), provides for review of a special master's decision by the Court of Federal Claims (42 U.S.C. § 300aa-12(e)), and allows appeal of the Court of Federal Claims's rulings to this Court. 42 U.S.C. § 300aa-12(f).

To receive compensation, a claimant must petition the Court of Federal Claims and show, by a preponderance of the evidence, that the vaccinated person received a vaccine covered by the Act and either: (1) suffered an injury or condition or a significant aggravation of a pre-existing injury or condition listed on the Vaccine Injury Table, 42 C.F.R. § 100.3 ("Table"), within the requisite time frame listed on the Table, in which case causation is presumed (a "Table injury"); or (2) suffered an injury or condition or a significant aggravation of a pre-existing injury or condition not on the Table (a "non-Table injury"), in which case causation must be proven ("actual causation" or "causation-in-fact"). *See id.* at §§ 300aa-11(c)(1)(C), 300aa-14; 42 C.F.R. § 100.3 (2008). Under either approach, compensation is awarded only if the finder of fact concludes "that the petitioner has demonstrated by a preponderance of the evidence" entitlement to compensation, and also finds "that there is not a preponderance of the evidence"

showing that the injuries were "due to factors unrelated to the administration of the vaccine." 42 U.S.C.§§ 300aa-13(a)(1)(A), 300aa-13(a)(1)(B); *see also Hines v. HHS*, 940 F.2d 1518, 1524-25 (Fed. Cir. 1991).

B. Nature of the Case.

This is a case brought under the Vaccine Act seeking compensation for an injury (a neurological condition for which no specific diagnosis has been identified) that is not listed on the Table. The statutory benefits of presumed causation, which are reserved for Table injuries, were therefore not available to petitioners here. To receive compensation for J.H.'s alleged non-Table injury, it was petitioners' burden to demonstrate by a preponderance of the evidence, either through medical records or an expert medical opinion, that one or more vaccinations covered by the Act and administered to J.H. caused her alleged neurological condition. 42 U.S.C.§§ 300aa-11(c)(1)(C), 300aa-13(a)(1)(A).

To prove actual causation in this non-Table injury case, petitioners were required to:

> show by preponderant evidence that the vaccination brought about [J.H.'s] 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 the vaccination and the injury.

Moberly v. HHS, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting *Althen v. HHS*, 418 F.3d 1274,1278) (Fed. Cir. 2005)). Petitioners were not required to prove vaccine-causation to a level of scientific certainty. Rather,

> the burden of showing something by a preponderance of the evidence, the most common standard in the civil law, simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence.

Moberly, 592 F.3d at 1322 n.2 (Fed. Cir. 2010) (quoting *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 622 (1993)).

Even under the preponderance standard, however, the special master was required to assess the reliability of petitioners' evidence by looking for sound and reliable medical or scientific support. *Moberly*, 592 F.3d at 1325 ("[W]e have made clear that the special masters have that responsibility in Vaccine Act cases.") (citations omitted); *see also* Rules of the United States Court of Federal Claims ("RCFC"), Appendix B, Vaccine Rule 8(b)(1) (instructing special masters to consider only "relevant and reliable evidence"); *LaLonde v. HHS*, 746 F.3d 1334, 1341 (Fed. Cir. 2014) ("In Vaccine Act cases, petitioners must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation under the preponderance of the evidence standard.").

C. Course of Proceedings and Disposition in the Court Below.

Petitioners filed their Vaccine Act petition on May 8, 2006, initially alleging that a series of vaccinations administered to J.H. in 2004 caused her to experience "a degeneration of her motor skills and body control noticeable after mid-October 2004." A4. On July 14, 2006, the Secretary filed her response to the petition, contesting entitlement to compensation. *Id.* Petitioners subsequently amended their petition on March 5, 2007, to allege that J.H. "progressed normally for about over ten months, i.e. at least until October 14, 2004," and specifically identified two half-doses of influenza ("flu") vaccine administered to J.H. on October 14 and November 16, 2004, as the cause of her condition. *Id*.

On August 28, 2008, the parties participated in a fact hearing to address inconsistencies between notations in the medical records and petitioners' allegations regarding the timing of onset of J.H.'s condition. A4. Petitioners both testified at the hearing. *Id*. Following the hearing, the special master then assigned to the case, Special Master Richard Abell, ruled that the onset of J.H.'s condition occurred between July 16 and October 14, 2004, prior to her receipt of the first half-dose flu vaccination. *Id*. More specifically, the special master found that the onset of J.H.'s developmental delays occurred between six and nine months of age, based on notations in J.H.'s medical records noting concerns regarding her

development well before her receipt of the first half-dose flu vaccine. *Id*. Special Master Abell subsequently retired, and the case was reassigned to another special master, Special Master George L. Hastings. *Id*.

On January 9, 2012, petitioners submitted an expert report from pediatric immunologist James Oleske, M.D. A5. The Secretary responded with an expert report from pediatric immunologist Stephen McGeady, M.D. *Id*. Petitioners then submitted an additional report from Dr. Oleske to respond to matters raised by Dr. McGeady. *Id*. The special master conducted an evidentiary hearing on December 5, 2012, at which Drs. Oleske and McGeady testified. *Id*. The parties each filed briefs following the hearing. *Id*.

On August 26, 2014, the special mater issued a decision denying entitlement to compensation. A1-20. The special master concluded: "After carefully considering all of the evidence in the record, I must reject Petitioners' claim that [J.H.'s] degenerative neurological disorder was caused or exacerbated by the two half-doses of influenza vaccination that J.H. received on October 14 and November 16, 2004." A7. The special master based his decision that petitioners failed to prove their claim on several factors. First and foremost was the fact that J.H.'s condition more likely than not predated her vaccinations. A11-13. The special master determined that because "Dr. Oleske based his causation opinion on the

clearly incorrect assumption that J.H.'s neurological demise began *after* the influenza vaccination of October 2004, Dr. Oleske's causation opinion may be *rejected for that reason alone*." A13 (emphasis in original). The special master further found that Dr. McGeady's testimony was "more persuasive in general," and that Dr. Oleske "simply failed to put forth any coherent presentation of *evidence or reasoning* to support his causation conclusion." *Id*. (emphasis in original). Specifically, the special master found that Dr. Oleske's opinion that J.H.'s condition resulted from dysfunction in her immune system amounted to nothing more than speculation, and that his "challenge-rechallenge" causation theory was not supported by the facts of the case. A13-15. Consequently, the special master held that petitioners failed to establish any of the three prongs of the causation-in-fact test, noting that it was "*not* a close case." A19-20 (emphasis in original).

Petitioners timely sought review by the Court of Federal Claims. On December 4, 2014, Court of Federal Claims Judge Charles F. Lettow issued an Opinion and Order affirming the special master's decision. A21-33. As an initial matter, Judge Lettow found that "the special master's conclusion regarding the onset of J.H.'s symptoms is supported by both the facts and the record." A29. Judge Lettow also found no error in the special master's analysis of "petitioners' various theories of causation," holding that "the special master weighed the

evidence of record and made determinations in accord with law." A30, 33. In addition, Judge Lettow addressed petitioners' argument, raised for the first time on appeal, that "an autoimmune reaction to the flu vaccine may have exacerbated an underlying condition, resulting in J.H.'s neurological decline." A31. Noting that "petitioners waited to raise a significant-aggravation claim until after a decision was rendered by the special master following the conclusion of percipient witness and expert testimony," and that "no testimony whatsoever has been presented on a significant-aggravation theory by an expert witness," Judge Lettow "decline[d] to permit petitioners to amend their petition to incorporate a significant-aggravation claim at this stage of the proceedings." A32-33. The Court of Federal Claims entered judgment dismissing the petition on December 5, 2014. A34. On January 26, 2015, petitioners timely filed their Notice of Appeal.

IV. STATEMENT OF THE FACTS

The relevant facts are primarily those found by the special master in his August 26, 2014, decision. A5-7. J.H. was born on January 12, 2004, along with her twin brother. A5. She had well-child examinations at sixteen days and age six months; no concerns regarding her development were noted during this time period. *Id.* J.H. received vaccinations on March 15, May 17, and July 16, 2004, with no adverse reaction to any vaccine recorded in the medical records. *Id.*

During her six-month pediatric visit on July 16, 2004, J.H.'s pediatrician noted on a checklist that J.H. was rolling over in both directions and "sits with support/alone." A5. However, when she returned on October 14, 2004, concerns about developmental delays were noted. *Id*. Specifically, the medical records state that J.H. was not rolling over and not sitting alone, indicating a loss of skills from her previous visit. *Id.* A medical note on October 14, 2004, also indicated that J.H. had decreased muscle tone. *Id*. During this October 14 visit, J.H. was administered the first half-dose of flu vaccine. *Id.* On November 16, 2004, J.H. received the second half-dose of flu vaccine. *Id*. The next day, she was referred for occupational and physical therapy, and thereafter referred to a neurologist. A42.

On December 20, 2004, J.H. had her initial evaluation by pediatric neurologist, Dr. Stumpf. A5. Dr. Stumpf noted that J.H. was socially and cognitively age-appropriate, but he diagnosed J.H. with spastic diplegia and cerebral palsy. A5-6. Dr. Stumpf opined that J.H.'s cerebral palsy stemmed from "twinning." A6.

At a 12-month well-child examination on January 18, 2005, it was noted that J.H. was unable to pull to a stand, walk independently, or grasp objects. A6. The doctor's assessment was "well developed but with muscle weakness and motor

delay." *Id.* Other early 2005 medical records noted that J.H. was "not using her bilateral extremities as functionally as she used to," but that her parents noted improvements with prone activity, sitting and kicking since initiating physical therapy. *Id.*

J.H.'s neurological condition deteriorated over the ensuing year. During that time she was evaluated by numerous physicians, including neurologists, geneticists, pediatricians, orthopedic surgeons and physical and rehabilitation specialists at Children's Memorial Hospital. A6. In late March 2005, J.H.'s parents and physical therapists noted a loss of milestones, difficulty feeding, and the onset of clenched fists. *Id.* An examination by Dr. Stumpf in April 2005, revealed a significant increase in spasticity. *Id*. Due to her rapid decline, Dr. Stumpf recommended additional testing to determine whether J.H. had a degenerative disorder. *Id.*

By June 2005, J.H. had deteriorated to the extent that she had very poor head control and trunk control. A6. At that time, she was diagnosed with spastic quadriplegia, etiology unclear. *Id.* Even with physical therapy, J.H.'s motor function continued to worsen. *Id.* In November 2005, J.H. was evaluated at the Mayo Clinic. *Id*. Despite extensive testing, no diagnosis was confirmed. *Id.* To date, there has been no definitive diagnosis for J.H.'s condition. A7.

V. SUMMARY OF THE ARGUMENT

The special master's decision reflects a thorough and careful evaluation of the record as a whole, and the special master had sound reasons for finding that Dr. Oleske's opinion was unpersuasive and, therefore, insufficient to satisfy petitioners' burden of proof. Petitioners' arguments amount to nothing more than rearguing evidence that the special master considered and rejected. Petitioners have simply failed to establish any error in the special master's decision. In addition, just as they did with their significant aggravation argument in their appeal to the Court of Federal Claims, petitioners have improperly advanced for the first time in this appeal an entirely new argument, based on an entirely different vaccine than their expert focused on below. The Court should disregard this new argument, as it is waived. But even if the Court were to consider the argument, it is based on a fundamental misunderstanding of the law, is unsupported by the record evidence, and provides no grounds for disturbing the special master's decision.

VI. STANDARD OF REVIEW

This Court reviews de novo a ruling by the Court of Federal Claims on a special master's decision to grant or deny entitlement to compensation under the Vaccine Act. *Lampe v. HHS*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (citing *Bradley*

v. HHS, 991 F.2d 1570, 1574 (Fed. Cir. 1993)). In other words, in reviewing a ruling of the Court of Federal Claims, this Court "performs the same task as the Court of Federal Claims and determines anew whether the special master's findings were arbitrary and capricious." *Id.*; *see also Hines*, 940 F.2d at 1524 (holding that the Federal Circuit reviews de novo the Court of Federal Claims's "determination as to whether or not the special master's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").

Whether the special master applied the appropriate standard of causation is a legal determination reviewed by this Court de novo under the "not in accordance with law" standard. *See Munn v. HHS*, 970 F.2d 863, 870-73 (Fed. Cir. 1992). However, this Court is to apply the arbitrary and capricious standard to fact findings, and the special master's discretionary rulings are to be reviewed under the abuse of discretion standard. *Id*. at 870 n.10. As this Court has held:

> Congress assigned 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 Master's fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. Our cases make clear that, on review . . . 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. HHS, 9 F.3d 958, 961 (Fed. Cir. 1993) (internal citations omitted).

Thus, this Court does "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. HHS*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing *Broekelschen v. HHS*, 618 F.3d 1339, 1349 (Fed. Cir. 2010) (citing *Munn*, 970 F.3d at 871)). As long as a special master's factual findings are "based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary and capricious." *Cedillo v. HHS*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d 1363). In general, reversible 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*, 940 F.2d at 1528.

VII. ARGUMENT

A. The Court Should Disregard Petitioners' Newly-Raised Argument.

As noted in the special master's decision, Dr. Oleske's opinion in this case identified the two half-doses of flu vaccine that J.H. received in October and November 2004 as causative of her condition, and was premised on an assumption that J.H.'s condition arose subsequent to those vaccinations. A8. The special master's rejection of Dr. Oleske's causation opinion was based in substantial part

on the fact that both he and the prior special master assigned to the case found that preponderant evidence established that the onset of J.H.'s condition occurred between July and October 2004, before J.H. had received the flu vaccinations. A13. In seeking review of the special master's decision before the Court of Federal Claims, petitioners attempted to change course to address this problem in their case, arguing for the first time that the half-dose flu vaccinations significantly aggravated a pre-existing condition. A31. Judge Lettow rightly rejected petitioners' attempt to raise a significant aggravation claim for the first time on appeal (A31-33), and petitioners have not challenged Judge Lettow's ruling in that regard in their appeal to this Court.

Instead, petitioners now appear to advance a new argument altogether to account for the earlier onset of J.H.'s condition. Petitioners' argument is somewhat difficult to follow, but they appear to argue that the symptoms J.H. experienced between six and nine months "are consistent with a DTaP injury," and obliquely assert that the DTaP vaccine administered on July 14, 2004, "may have played some role in her deterioration." Brief for Petitioners-Appellants ("P's Br.") at 19-21. While petitioners alleged in their petition that J.H.'s condition was caused by "a series" of vaccines administered to her, of which DTaP was one, petitioners did not develop the argument before the special master that the DTaP

vaccine "may have played some role in her deterioration." Therefore, it has been waived, and the Court should disregard it. *See* RCFC, Appendix B, Vaccine Rule 8(f); *see also Veryzer v. HHS*, 100 Fed. Cl. 344, 354 (2011) (holding that the petitioner failed to properly preserve the argument that an alternate vaccine caused the injury), *aff'd per curiam*, 475 Fed. Appx. 765 (Fed. Cir. 2012).

Even if not waived, however, petitioners' argument finds no basis in the factual record. To the extent petitioners are suggesting that the DTaP vaccine played some role in causing J.H.'s condition, petitioners themselves make it clear that the record evidence does not support any such claim. They acknowledge that their own expert, Dr. Oleske, deemed the evidence "insufficient for him to make that association." P's Br. at 20. Petitioners also cannot have it both ways. They cannot simultaneously argue that the July 2004 DTaP vaccine caused J.H.'s developmental delays that occurred between July and October 2004, and at the same time argue that the special master was arbitrary and capricious in finding that the onset of J.H.'s developmental delays occurred during that same time period. It is clear that petitioners are simply trying to shoe-horn the facts into some argument that might persuade the Court, but in doing so petitioners actually expose the incoherence of, and lack of support for, their evolving positions.

Petitioners' argument also misconstrues the law and the record below. Petitioners incorrectly assert that "it was the respondent's burden to establish not only that the injury arose before the flu vaccination but that the flu vaccine's effects were immaterial, and that the July vaccinations did not cause the injury." P's Br. at 22-23. In making this argument, petitioners repeatedly claim that the special master concluded that J.H.'s condition was "idiopathic" (which means without a known cause) in determining that it arose before her flu vaccinations. Arguing that the special master committed error, they assert that a "decision finding an earlier idiopathic onset following the July vaccines, without evidence satisfying any of these criteria, is arbitrary and capricious." *Id*. at 23. As an initial matter, the special master did not describe J.H's condition is "idiopathic." More importantly, petitioners confuse the issue of time of onset with evidence of an alternate cause, in an unsuccessful attempt to establish that the Secretary assumed a burden to prove a "factor unrelated" to the flu vaccinations caused J.H.'s injury. P's Br. at 19.

The Secretary did not argue an earlier onset of J.H.'s condition in an effort to prove an alternate cause of her condition. Rather, the Secretary argued that given the evidence of an earlier onset of J.H.'s condition, the subsequent flu vaccinations necessarily could not have caused it. In other words, the Secretary's

evidence regarding onset was offered to rebut petitioners' theory of causation, not to prove an alternate cause. *de Bazan v. HHS*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief.") Indeed, where, as here, a petitioner fails to make a *prima facie* showing of causation, the Secretary is under no burden to prove another cause of the injury, and special masters are authorized to consider rebuttal evidence submitted by the Secretary in determining whether a petitioner has proven a *prima facie* case. *Stone v. HHS*, 676 F.3d 1373, 1379-80 (Fed. Cir. 2012) (citing other cases), *reh'g en banc denied*, 690 F.3d 1380 (Fed. Cir. 2012), *cert. denied sub nom. Stone v. Sebelius*, 133 S.Ct. 2022 (Apr. 29, 2013); *see also de Bazan*, 539 F.3d at 1353. Petitioners' attempt to shift the burden to the Secretary is simply wrong.

At bottom, petitioners' attempt to shift the Court's focus to the July 2004 DTaP vaccine as a means of concealing the problems inherent in the case they presented to the special master fails.

B. The Special Masters' Factual Finding That J.H.'s Condition Predated Her October 14, 2004 Vaccination Is Amply Supported And Entitled To Deference.

Two different special masters found in the course of the proceedings below that the onset of J.H.'s neurological decline occurred between July and October

2004, prior to her first flu vaccine on October 14, 2004. A5-7, 10-12. That factual finding, affirmed by the Court of Federal Claims, is more than amply supported by the evidentiary record, and must be sustained.

The timing of the onset of J.H.'s condition became an issue very early in the case. While the first special master (former Special Master Abell) afforded petitioners a full and fair opportunity to testify about their recollection of when J.H.'s symptoms began, Special Master Abell ultimately found more persuasive the contemporaneous medical records, which placed the onset of J.H.'s developmental delays between six and nine months of age, prior to the receipt of the October 14, 2004, vaccine. A11; *see also* A46 (Findings of Fact).[1] The special master's weighing of the evidence was not an abuse of discretion and is squarely in accordance with the law. *See* 42 U.S.C. § 300aa-13(a)(1); *see also Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (holding that medical records "warrant consideration as trustworthy evidence").

In his decision on entitlement, Special Master Hastings examined the findings of Special Master Abell and conducted his own thorough comparison of

[1] Although Dr. Oleske filed two reports in this case, neither referenced the Findings of Fact issued two years earlier by Special Master Abell. Dr. Oleske's opinion that the onset of J.H.'s neurological condition followed each of her flu vaccinations was based upon the factual assertions offered by petitioners, which were rejected by the special masters in light of the more persuasive medical records.

the medical records with the transcript testimony presented by petitioners. A12. Based on this review, Special Master Hastings concluded that he "concur[red] entirely with Special Master Abell's comparison of the records made in July and October of 2004, and his firm conclusion from those two records." A12.

In addition, Special Master Hastings found the testimony of respondent's medical expert, Dr. McGeady, persuasive with regard to the onset of J.H.'s neurological condition. Dr. McGeady testified that the medical records reflected that between July 2004 and October 14, 2004, J.H. experienced a loss of previously acquired developmental skills including the ability to sit up and roll over. A10. Moreover, by October 14, 2004, J.H. had developed decreased muscle tone. *Id.* Dr. McGeady testified that for an infant "not to have made significant physical skill acquisition between the ages of six and nine months (July to October) would be highly abnormal, and to have *lost* skills in that same time period would be alarming." *Id.* (emphasis in original). His opinion further supported the special master's determination that the onset of J.H.'s neurological condition occurred prior to the receipt of her October 14, 2004, half-dose flu vaccination.

Finally, Special Master Hastings noted that Special Master Abell also considered later histories offered by petitioners to medical providers. A12. Several of these histories, including those given to providers at the Mayo Clinic,

reported that J.H.'s development began to fall behind the progress of her twin brother at about six months of age, or in July 2004. *Id.* It is thus clear from his decision that the special master considered the medical records as a whole and the persuasive testimony of Dr. McGeady to conclude that J.H.'s neurological symptoms occurred prior to the administration of her October 14, 2004, flu vaccine. A10-12.

In sum, as Judge Lettow correctly held, the special master's assessment of the evidence and his findings regarding the onset of J.H.'s neurological condition are well-supported by the record. Petitioners disagree with the special master's findings of fact, but they articulate no reversible error, seeking only to have this Court impermissibly re-weigh the evidence that has been carefully examined by the special master in an effort to obtain a different result. Petitioners' efforts to re-litigate the facts of this case on appeal must be rejected. *See Munn*, 970 F.2d at 871.

C. The Special Master Correctly Rejected Petitioners' Theory of Challenge-Rechallenge.

Petitioners incorrectly assert that the special master "failed to comprehend that re-challenge alone is conclusive proof of causation, without more," and thereby "rendered the petitioners' burden impossible." P's Br. at 23. In fact, contrary to petitioners' assertion that the special master heightened their burden,

the special master specifically acknowledged that evidence of challenge-rechallenge can be "powerful evidence of causation." A15. However, after reviewing the evidence proffered by petitioners' expert, he found that J.H's condition did not fit the challenge-rechallenge model. A16. He explained that Dr. Oleske's reports did not adequately discuss challenge-rechallenge, and his testimony failed to explain to what extent he relied upon this concept in concluding that J.H. suffered an autoimmune reaction to her flu vaccinations. A15.

Moreover, the special master found the testimony of Dr. McGeady more persuasive in determining that the underlying factual assumptions relied upon by Dr. Oleske in forming his opinion were incorrect – that the onset of J.H.'s neurological condition occurred after her October 2004 flu vaccination, and that she exhibited a rapid turn for the worse in her symptoms after both of the vaccinations in question. A15. In addition to the special master's findings with regard to onset, based upon his review of the medical records and the testimony of Dr. McGeady, the special master determined that the medical records did "*not* indicate any sharp change in J.H,'s neurological symptoms after either her October or November influenza vaccinations." *Id.* As the special master noted, when J.H. first saw a neurologist in December 2004, the history reported of J.H.'s neurological problems did not mention either of the flu vaccinations, or indicate

that the onset of J.H.'s neurological symptoms occurred in October 2004, or that her neurological symptoms worsened soon after her second flu shot in November 2004. A12 n.7. For these reasons, the Special Master determined that the facts of this case did not fit the challenge-rechallenge scenario. A15-16 ("[A]fter closely studying the record in this case, I firmly conclude that the 'challenge/rechallenge' concept does *not* apply to this case."). Judge Lettow correctly upheld this determination (A31), and the Secretary respectfully requests that this Court do the same.

D. The Special Master Did Not Err In Finding That Petitioners' Evidence Failed To Satisfy Their Burden Of Proof.

Petitioners finally argue that because their autoimmune theory is plausible, the record evidence establishes temporal proximity between vaccination and onset, and there is no identifiable alternate cause of J.H.'s condition, they have met their burden of proof. This argument is without merit for three reasons.

First, petitioners have not established that their autoimmune theory is plausible as applied to this case. *See*, *e.g.*, *Broekelschen*, 618 F.3d at 1345 (holding that "a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Here, the special master found that Dr. Oleske failed to provide any support for petitioners' autoimmune theory:

> Dr. Oleske never explained *why* he thought that influenza vaccine might be capable of causing an unusual immunological response that could lead to the type of severe neurological demise such as the one J.H. suffered. He never pointed to any medical literature supporting his reasoning on this point. His opinion seemed to amount to mere speculation, or guesswork. . . . In short, there is no significant evidence that J.H. even has an immune dysfunction. And even if she did, Dr. Oleske has provided no evidence for his speculation either (1) that the *influenza vaccinations* cause such immune dysfunction, or (2) that such immune dysfunction contributed to her *neurological* disorder.

A14 (emphasis in original). Second, as the special master correctly found, the record evidence does not establish an appropriate temporal relationship between J.H.'s vaccinations and the onset of her symptoms.

Finally, this Court has repeatedly rejected petitioners' formulation of their legal burden asserted here. *See, e.g.*, *Hibbard v. HHS*, 698 F.3d 1355, 1366 (Fed. Cir. 2012) ("This court has previously rejected the same argument – that proof that an injury could be caused by a vaccine and that the injury occurred within an appropriate period of time following the vaccination is sufficient to require an award of compensation unless the respondent can prove some other cause for the injury."); *Moberly*, 592 F.3d at 1323 ("As this court has stated, 'neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation.'" (citing *Althen*, 418 F.3d at 1278)).

VIII. CONCLUSION

Based on a thorough review of the record evidence submitted by both parties, the special master concluded that petitioners' expert, Dr. Oleske, failed to provide a persuasive causation opinion, and the evidence therefore preponderated against a finding of entitlement to compensation. Indeed, the special master determined that it was not even a "close case." A20. As Judge Lettow held, the special master correctly applied the law and provided sound reasons for his findings, which were supported by the record evidence. The Secretary therefore respectfully requests that this Court affirm the decisions below.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify, based on the line count of the word-processing system used to prepare this brief, that the brief contains 5,337 words and 472 lines of text, and is, therefore, in conformity with Fed. R. App. P. 32(a)(7)(B).

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CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of May, 2015, the foregoing **BRIEF OF RESPONDENT-APPELLEE** was served electronically upon:

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Paper copies will also be mailed to the above counsel at the time paper copies are sent to the Court.