

No. 92-764 V
(Filed: December 3, 1997)

WILLIAM L. McCARREN, SR., and *
PATRICIA A. McCARREN for *
WILLIAM L. McCARREN, JR., *

Petitioners, *

v. *

SECRETARY OF THE DEPARTMENT *
OF HEALTH AND HUMAN SERVICES, *

Respondent. *

* National Childhood Vaccine
* Injury Act; Standard of
* Review; Burden of Proof.

E. James Thompson, Jr., Baltimore, MD, for petitioners.

Glenn MacLeod, Washington, D.C., with whom were *Assistant Attorney General Frank Hunger*,
Acting Director John Lodge Euler, and *Assistant Director Gerard W. Fischer*, for respondent.

ORDER

TIDWELL, Judge:

This case is before the court on petitioners' motion for review of Chief Special Master Gary J. Golkiewicz's June 6, 1997, decision denying compensation under the National Childhood Vaccine Injury Act of 1986, Pub. L. No.99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-1 to 300aa-34 (1994 & Supp. 1995)) ("Vaccine Act"). For the reasons set forth below, the court denies petitioners' motion for review and affirms the Chief Special Master's decision.⁽¹⁾

FACTS

The specific facts of this case are set forth in the Chief Special Master's published decision, *McCarren v. Secretary of Dep't of HHS*, No. 92-764V, 1997 WL 341694 (Fed. Cl. Sp. Mstr. June 6, 1997). The court

will only discuss those facts necessary for disposition of petitioners' motion.

On November 3, 1992, petitioners, William L. McCarren, Jr. ("Billy") and his parents, filed a claim pursuant to the Vaccine Act, alleging that Billy contracted a residual seizure disorder and encephalopathy as a result of the Diphtheria-Pertussis-Tetanus ("DPT") vaccination he received on March 13, 1990. On March 16, 1990, approximately 80 hours after receiving the vaccination, Billy (herein referred to as claimant) suffered a seizure. He was subsequently diagnosed with an intractable seizure disorder. Following the filing of expert reports by both parties, the Chief Special Master conducted a hearing on October 12, 1994. A second hearing, held on November 5, 1996, was limited to the question of whether the DPT vaccination was the cause-in-fact of claimant's disorder. Post hearing briefs were submitted by both parties. On June 6, 1997, the Chief Special Master denied petitioners' claim.

DISCUSSION

I. Standard of Review

The Vaccine Act establishes the standard this court is to employ when reviewing the determinations of a special master. The court has jurisdiction to "set aside any findings of fact or conclusion of law of the special master found to be arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusion of law." 42 U.S.C. § 300aa-12(e)(2)(B) (1994). Nevertheless, there has been considerable disagreement regarding the appropriate standard of review for legal determinations. *Compare Charette v. Secretary of Dep't of HHS*, 33 Fed. Cl. 488, 490 (1995) ("By the plain language of the statute, *de novo* review . . . is not appropriate."), and *McClendon v. Secretary of Dep't of HHS*, 28 Fed. Cl. 1, 6 (1993) (stating that the court will not review questions of statutory interpretation *de novo*, and will instead grant the special master substantial deference), *aff'd*, 41 F.3d 1521 (Fed. Cir. 1994), and *Sharpnack v. Secretary of Dep't of HHS*, 27 Fed. Cl. 457, 459 (1993) (finding *de novo* review to be "contrary to the language of the statute"), *aff'd*, 17 F.3d 1442 (Fed. Cir. 1994), with *Carraggio v. Secretary of Dep't of HHS*, 38 Fed. Cl. 211, 217 (1997) ("The Court reviews questions of statutory interpretation [under the Vaccine Act] *de novo*."), and *Buxkemper v. Secretary of Dep't of HHS*, 32 Fed. Cl. 213, 217 (1994) ("This court does not agree that . . . a *de novo* review of statutory construction is inappropriate"). For the reasons set forth below, this court finds that *de novo* review of the special master's interpretation of the Vaccine Act is inappropriate. Review of a special master's legal determinations in the Court of Federal Claims is of a limited, deferential nature.

The Vaccine Act's standard of review parallels the standard of review found in the Administrative Procedure Act ("APA"), which permits a court to set aside only those actions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A) (1994). Congress is presumed to be aware of the language and judicial interpretation of pertinent existing law when it passes new legislation, or makes amendments to existing legislation. *See Miles v. Apex Marine Corp.*, 498 U.S. 19, 32 (1990); *Cannon v. University of Chicago*, 441 U.S. 677, 696-97 (1979). In the absence of explicit evidence to the contrary, this court is unwilling to assume that Congress was ignorant of the nature of the standard of review it specified in the 1989 amendments to the Vaccine Act.

When the language of a statute is unclear, the court may consider legislative history as an aid to interpretation. *See Jones v. Brown*, 41 F.3d 634, 640 (Fed. Cir. 1994). Even where, as here, the statute is apparently unambiguous, legislative history can be used to confirm that the court's interpretation of the statute reflects congressional intent. *See Glaxo Operations U.K. Ltd. v. Quigg*, 894 F.2d 392, 395-96 (Fed. Cir. 1990). Prior to the 1989 amendments, the special master took evidence and *proposed* findings of fact and conclusions of law for consideration by the Claims Court judge. *See* 42 U.S.C. § 300aa-12(c) (2) (Supp. V. 1987) (amended 1989); *cf. Munn v. Secretary of Dep't of HHS*, 970 F.2d 863, 868 (Fed. Cir.

1992) (discussing the impact of the 1989 amendments on the Federal Circuit's standard of review). Upon receipt of the special master's proposal, the Claims Court judge was directed to "undertake a review of the record . . . and . . . *make a de novo determination of any matter* and issue its judgment accordingly. . . ." 42 U.S.C. § 300aa-12(d)(1) (amended 1989) (emphasis added).

Congress, unsatisfied with the review structure of the Vaccine Act, altered the relationship of the special master and the Claims Court. *See generally* 135 Cong. Rec. S29876-79 (daily ed. Nov. 17, 1989). Under the amended 42 U.S.C. § 300aa-12(d), the special master no longer makes proposed findings of fact or conclusions of law. *See* 42 U.S.C. § 300aa-12(d) (1994). The special master now "issue[s] a decision . . . with respect to whether compensation is to be provided under the program and the amount of such compensation." 42 U.S.C. § 300aa-12(d)(3)(A). In reviewing the decision of a special master, this court may take one of three specified actions:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusion of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). Conspicuously absent from the amended statute, and this court's standard of review, are the words *de novo*.

In enacting the 1989 amendments, Congress clearly articulated its desire to make review of a special master's decision an extraordinary event, stating that "the Conferees have provided for a *limited standard for appeal from the [special] master's decision and do not intend that this procedure be used frequently but rather in those cases in which a truly arbitrary decision has been made.*" H.R. Conf. Rep. No. 101-386, at 516-17, *reprinted in* 1989 U.S.C.C.A.N. at 3120 (emphasis added). The post-1989 Vaccine Act compensation program is a novel proceeding, with the special masters holding a unique role within the program's amended procedures. *See Skinner v. Secretary of Dep't of HHS*, 30 Fed. Cl. 402, 407 (1994). It is the special masters to whom Congress has accorded the status of expert, entitling them to the special statutory deference normally reserved for specialized agencies. *See Munn*, 970 F.2d at 871. As such, it is not surprising that Congress modeled the Vaccine Act's standard of review for statutory construction after the APA. This court believes that it is entirely reasonable to review issues of statutory construction with deference to the special master. Deference is frequently shown by the judiciary in the review of agency action under the APA, *see, e.g., Southern California Edison v. FERC*, 116 F.3d 507, 511 (D.C. Cir. 1997), and there is no reason to believe that an identical standard is impossible, or inappropriate, here. *But cf. Buxkemper v. Secretary of Dep't of HHS*, 32 Fed. Cl. 213, 217 (1994) ("[A] judge of this court ought to, and in any event will, conduct a *de novo* review of the meaning of the words of a statute").

The proper framework for statutory interpretation under the *otherwise not in accordance with the law* standard is found in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984). *Chevron* requires that the court consider the following:

First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. . . . [However,] if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Id. at 842-43.

Where clear, the unambiguously expressed intent of Congress prevails. Any conclusion of law or construction of a statute made by a special master that is contrary to the unambiguously expressed intent of Congress is *otherwise not in accordance with the law* and must, therefore, be rejected. Where the language of the statute is ambiguous, however, this court need not conclude that the special master's construction of the statute was the only one it could have adopted, or even the reading the court would have reached if the question initially had arisen within its purview. The interpretation need only be reasonable. *See Chevron*, 467 U.S. at 843 n.11; *McClendon*, 28 Fed. Cl. at 5 (1993) (quoting *Chula Vista City Sch. Dist. v. Bennett*, 824 F.2d 1573 (Fed. Cir. 1987)). Thus, where the Vaccine Act is silent or ambiguous with respect to the specific issue, the special master's interpretation is given deference. *Cf. Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 414 (1993) ("Confronted with an ambiguous statutory provision we generally will defer to a permissible interpretation espoused by the agency entrusted with its implementation."); *National R.R. Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407, 417-18 (1992). As such, this court will not reject a conclusion of law by the special master unless it contravenes a statutory provision, a clearly-discernable legislative intent, or is otherwise unreasonable or irrational.

II. Recovery Under the Vaccine Act

Under the Vaccine Act, claimants may pursue compensation for a vaccine-related injury or death in two ways. Causation may be presumed if the claimant establishes, through medical records or expert testimony, a claim of an injury listed on the Vaccine Injury Table ("Table"), 42 U.S.C. § 300aa-14(a), and shows by a preponderance of the evidence that the injury occurred within the time period prescribed by the Table. *See* 42 U.S.C. § 300aa-13(a)(1)(A). The Table "determines by law that the temporal association of certain injuries with the vaccination suffices to show causation . . . [replacing] traditional tort standards of causation in fact with a causation in law based on temporal association." *Grant v. Secretary of Dep't of HHS*, 956 F.2d 1144, 1147 (Fed. Cir. 1992).

Alternatively, claimants may recover under the Vaccine Act by showing causation-in-fact if the injury is either not included in the Table, or if a listed Table injury occurred after the corresponding time period has run. *See* 42 U.S.C. § 300aa-11(c)(1)(C). Compensation for non-Table injuries is authorized under 42 U.S.C. § 300aa-11(c)(1), and includes any illness, disability, injury, or condition not listed on the Table or not meeting the Table's requirements. Causation-in-fact is more difficult to establish because it requires the claimant to prove that the vaccine in question *actually caused* the claimed injury by a preponderance of the evidence -- the presumption of causation that exists with a Table injury is not available. Though it is not necessary to show that the vaccination caused the injury with scientific certainty, a mere temporal association between the injury and the vaccination is not enough. *See Bunting v. Secretary of Dep't of HHS*, 931 F.2d 867, 873 (Fed. Cir. 1991). If a claimant substantiates a claim by either route, the burden of proof shifts to the government to prove that the illness, injury, or death is due to factors unrelated to the vaccine. *See* 42 U.S.C. § 300aa-13(a)(1)(B).

In the instant case, petitioners attempted to establish a Table injury under 42 U.S.C. § 300aa-14(a)(I), and, alternatively, causation-in-fact under 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(II). The Chief Special Master determined that claimant's injury did not manifest within the time limit required for a Table injury, and that he failed to meet the burden of proof required to establish causation-in-fact. *See McCarren*, 1997 WL 341694, at *16.

Petitioners object to the Chief Special Master's interpretation of the requirement, set forth in the Vaccine Injury Table, 42 U.S.C. § 300aa-14(a), that the onset of a residual seizure disorder following the

administration of a DPT vaccine must occur within "three days" to qualify as a table injury. The Chief Special Master concluded that "three days" meant 72 hours and not three calendar days. Acknowledging this court's acceptance of an identical interpretation by the Chief Special Master in *Ultimo by Ultimo v. Secretary of Dep't of HHS*, 28 Fed. Cl. 148 (1993), petitioners request that the court reconsider its position.

Interpretation of the time requirement set forth in the Table is crucial to this case. The record indicates that claimant's first seizure occurred on the third day, approximately 80 hours after receiving the DPT vaccination. If the Table requires the injury to manifest within 72 hours, claimant loses the presumption of causation from which he would benefit if the more liberal three calendar day interpretation applied. The legislative history of the Vaccine Act, unfortunately, provides no specific guidance on the proper interpretation of the time requirements listed in the Table.

Petitioners provide a variety of arguments to support their position that Congress may have intended the Table requirement to mean three calendar days and not 72 hours. Section 300aa-12(e)(2)(B) requires this court to review the Chief Special Master's interpretation of the Vaccine Act under the "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law" standard. While three calendar days is one reasonable interpretation of the Table, and conceivably an interpretation this court might adopt if the issue were to arise *de novo*, the Chief Special Master's interpretation is reasonable in light of the ambiguous statutory language and the relevant case law.⁽²⁾ By using "three day" and "72 hour" terminology interchangeably, numerous decisions by the Court of Federal Claims and the Federal Circuit appear to conclude that the proper interpretation of the Table time requirement is 72 hours. *See, e.g., Hellebrand v. Secretary of Dep't of HHS*, 999 F.2d 1565, 1567-68, 1570 (Fed. Cir. 1993); *Bradley v. Secretary of Dep't of HHS*, 991 F.2d 1570, 1574-75 (Fed. Cir. 1993); *Gurr v. Secretary of HHS*, 37 Fed. Cl. 314, 318 (1997); *Skinner*, 30 Fed. Cl. at 407 (1994).

Accordingly, the court declines to alter the position adopted in *Ultimo* that 72 hours is a reasonable interpretation of the Vaccine Act's "three day" requirement. The court, therefore, sustains the Chief Special Master's conclusion that claimant failed to demonstrate a Table injury.

Petitioners also argue that the Chief Special Master's decision was arbitrary and capricious because of his failure to recognize the logical sequence of cause and effect demonstrated by the evidence. At the outset, this court notes that the arbitrary and capricious standard is highly deferential to the special master. If the special master has considered the evidence, drawn plausible inferences from the relevant evidence, and articulated a rational basis for the decision, reversible error will be extraordinarily difficult to demonstrate. *See, e.g., Hines v. Secretary of Dep't of HHS*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). The court performs its analysis cognizant of the unique position and expertise of the special master under the Vaccine Act. In examining the Chief Special Master's decision, the court may not substitute its own judgment for that of the special master. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 413-16 (1971). The special master's determination may be overturned when the decision relies on factors beyond those intended by Congress, fails to consider an important aspect of the problem, offers an explanation of the decision which clearly runs counter to the weight of the evidence, or is so implausible that it could not be ascribed to a difference in view or a product of expertise. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29 (1983). In sum, establishing that the special master's factual conclusions were arbitrary and capricious is an extraordinarily difficult task. *See generally Munn*, 970 F.2d at 871 (discussing standard of review for factual questions under the Vaccine Act).

The Chief Special Master received and reviewed numerous expert reports from both parties. *See McCarren*, 1997 WL 341694 at *1-2. The Chief Special Master also held two hearings and received post-hearing briefs from both parties prior to issuing his decision. *See id.* In his twenty-three page decision, the Chief Special Master carefully considered the evidence presented by both parties and concluded that "the

weight of the evidence demonstrates that the DPT vaccination did not cause Billy's March 16th seizure, subsequent seizure disorder, and/or current encephalopathy." *Id.* at *16.

The Chief Special Master provided the following synopsis of the expert testimony:

(1) Dr. Woody [claimant's expert] and Dr. Frost [respondent's expert] could not identify an exact cause of the seizures, and neither testified, with any certainty, that Billy's current encephalopathy and/or seizure disorder were related to DPT, (2) Dr. Woody and Dr. Lavenstein [respondent's expert] suggested that the seizure disorder could have been a latent phenomenon, (3) Dr. Lavenstein testified that the initial seizure was due to the [otitis media] and fever spike, not the DPT vaccination, and the subsequent seizure disorder was due to some abnormality of the brain, also unrelated to the inoculation; moreover, Dr. Lavenstein found no evidence of an encephalopathic injury following the vaccination or in the few weeks following the first seizure, and (4) Dr. Gabriel [claimant's expert] connected Billy's encephalopathy and initial seizure/subsequent epilepsy to the DPT vaccination.

Id. Because Dr. Gabriel's testimony was based almost entirely on the temporal relationship between the vaccination and claimant's symptoms, the Chief Special Master found it unconvincing. *See id.* In particular, the Chief Special Master felt that Dr. Gabriel's bias in favor of DPT causation clouded his consideration of other medical possibilities for claimant's injuries, and merely amounted to an independent version of presumed causation on a timetable different from that expressly provided by the statute. *See id.* The Chief Special Master determined that the testimony of the three remaining experts was more credible and was made more reliable by their particular understanding that these "types of injuries [are] difficult to assess, . . . [and] they often occur in infancy for inexplicable reasons." *Id.* Concluding that Dr. Woody, Dr. Frost, and Dr. Lavenstein fairly and objectively considered the medical information and concluded that DPT could not be positively identified as the source of claimant's injuries, the Chief Special Master found that claimant failed to establish, by a preponderance of the evidence, the necessary cause and effect linkage between the DPT vaccination and claimant's neurological injuries. *See id.*

Petitioners contend, however, that they have met the four factors required to prove a logical sequence of cause and effect, and that the Chief Special Master erred in denying relief. Petitioners maintain that the four factors required to show causation-in-fact are (1) that it is medically possible for the vaccine to cause the injury, (2) that there is a temporal association between the vaccination and the illness, (3) that there are no other known causes for the illness, and (4) that there is a reasonable medical explanation and effect. *See, e.g., Strother v. Secretary of Dep't of HHS*, 18 Cl. Ct. 816, 819-22 (1989), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). Petitioners assert that proof of these factors satisfies the causation-in-fact inquiry, and that once these factors are established, denial of relief is arbitrary and capricious. This assertion is correct, so long as the respondent does not show, by a preponderance of the evidence, that the illness, injury, or death is due to a cause other than the vaccine. *See* 42 U.S.C. § 300aa-13(a)(1)(B); *Strother*, 18 Cl. Ct. at 822-24. The Chief Special Master, however, did not find that petitioners satisfied these requirements.

Under the Vaccine Act, the special master, as finder of fact, has broad discretion in determining credibility and drawing factual conclusions. Determinations of credibility are, therefore, uniquely within the purview of the special master. Congress further intended the special master to be an expert in disputes arising under the Vaccine Act. The special master is, therefore, in a unique and well-suited position to make determinations on the credibility of evidence. *See Burns v. Secretary of Dep't of HHS*, 3 F.3d 415, 417 (Fed. Cir. 1993).

While petitioners *presented* evidence to satisfy all four of the aforementioned factors, the Chief Special Master, in his role as fact-finder, did not find all of petitioners' evidence to be credible and reliable. *See McCarren*, 1997 WL 341694 at *16. In particular, the Chief Special Master found that there were other,

more likely causes for claimant's illness. *See id.* at *15-16. Furthermore, while noting that the injuries suffered by claimant could potentially be caused by the DPT vaccination, *see id.* at *12, the Chief Special Master did not find that petitioners established, by a preponderance of the evidence, the necessary cause and effect linkage between the vaccination and claimant's neurological injuries. *See id.* at *14.

Despite petitioners' argument to the contrary, causation-in-fact is not established where the special master merely concludes that it is within the realm of medical possibility for the vaccine to cause the sustained injury. Nor is causation-in-fact satisfied where, as here, the special master determines that there is another known or likely cause for the illness, supported by credible expert testimony, or where the claimant fails to provide a reputable medical or scientific explanation, beyond mere temporal proximity, for the alleged sequence of cause and effect. *See Grant*, 956 F.2d at 1148.

We are satisfied that the Chief Special Master carefully considered the testimony of the four expert witnesses, weighed the evidence, and concluded that petitioners had not established causation-in-fact. The Chief Special Master's decision properly relies on the factors set forth by Congress, evaluates the important aspects of the case, offers a detailed explanation of the decision which is supported by the evidence, and is not implausible. As such the Chief Special Master's decision is not arbitrary or capricious.

CONCLUSION

Upon review of the Chief Special Master Golkiewicz's decision and applicable case law, the court finds that petitioners have failed to demonstrate that denial of their claim was arbitrary, capricious or otherwise not in accordance with the law. As a result, petitioners' motion for review

is denied. The court, pursuant to 42 U.S.C. § 300aa-12(e)(2)(A), hereby sustains the Chief Special Master's June 6, 1997, decision. The Clerk of the court is directed to enter judgment accordingly.

IT IS SO ORDERED.

MOODY R. TIDWELL
Judge

- ¹ Consequently, petitioners' September 22, 1997, request for an oral argument is denied.
- ² Petitioners argue that a 72 hour time limit unfairly places the burden of causation on an entire group of claimants who suffer undisputed seizure disorders on the third day, but more than 72 hours, following a DPT vaccination. Petitioners claim that nothing in the Vaccine Act (including the aids to interpretation of the Table found at 42 U.S.C. § 300aa-14(b)) suggests that Congress intended this result.

The purpose of the Table is to facilitate the adjudication of claims under the Vaccine Act where causation can be established through the mere temporal relationship between injury and vaccination. *See H.R. Rep. No. 99-908*, at 18 (1986). The time periods listed on the Table are based upon available scientific and medical knowledge. *See id.* Considering the purpose of the Table, the Chief Special Master's interpretation in this case is clearly reasonable. His conclusion, that "three days" means 72 hours, comports with the medical basis on which the Table has been formulated. In effect, the Table declares

that a listed injury occurring within 72 hours of the administration of a vaccine is so medically likely to have been caused by the vaccination that causation is presumed.

Petitioners' interpretation that "three days" means anytime within the third day following the vaccination, cannot be as easily squared with the medical and scientific basis of the Table. Under petitioners' view, two similarly situated children, inoculated at the same hospital on the same day with vaccines from the same manufacturer's lot, who contract the same condition, would face different evidentiary standards under the Vaccine Act depending on the time of day the vaccine is administered. If one child received the injection at 9:00 a.m. and had the first symptoms of a reaction 86 hours later, at 11:00 p.m. on the third day, the child would benefit from the presumption of causation under the Act. If the second child, however, received the injection at 4:00 p.m. and came down with identical symptoms 86 hours later, the child would not receive the same presumption. Even if the second child exhibited symptoms 5 hours earlier than the first child, the second child still would not receive the presumption of causation, merely because the second child received the shot in the afternoon. Petitioners fail to articulate, and this court cannot surmise, a rational medical or scientific basis for such an arbitrary system of compensation.