In the United States Court of Federal Claims

No. 99-480V
Filed: July 25, 2003

NANCY GARDNER-COOK, **Petitioner,** **v.** **SECRETARY OF HEALTH AND HUMAN SERVICES,** **Respondent.**	**Motion for Review of Special Master's Decision, National Vaccine Compensation Act, 42 U.S.C. §§ 300aa-1 to 300aa-34; Standard of review.**

DANIEL H. SHERTZER, SR., Lancaster, Pennsylvania, for petitioner.

MICHAEL P. MILMOE, Senior Counsel; **HELENE M. GOLDBERG**, Director, Torts Branch, Civil Division; **ROBERT D. McCALLUM, JR.**, Assistant Attorney General, United States Department of Justice, Washington, D.C., for respondent.

O R D E R

HORN, J.

Nancy Gardner-Cook, petitioner, alleged neurological injury after two hepatitis B vaccinations that she received on August 12 and September 9, 1994. Petitioner filed a claim in the United States Court of Federal Claims, seeking recovery under the National Childhood Vaccine Injury Act (Vaccine Act), 42 U.S.C. §§ 300aa-1 to 300aa-34 (2000). A special master dismissed petitioner's claim after hearing testimony and reviewing documents submitted by petitioner and respondent. Petitioner subsequently filed a timely motion for review in the United States Court of Federal Claims, objecting specifically to certain findings of the special master. This court has jurisdiction under the Vaccine Act to review the special master's findings of fact and conclusions of law. See 42 U.S.C. § 300aa-12(e)(2).

FINDINGS OF FACT

Nancy Gardner-Cook is a mother and medical secretary with a history of medical problems. Ms. Gardner-Cook received two hepatitis B vaccinations on August 12, 1994 and September 9, 1994, which she alleged caused neurological injury. Petitioner alleged that injuries resulting from the vaccinations have decreased her cognitive ability and work productivity, such that "[s]ince the vaccinations, she has been unable to keep employment," whereas past employers evaluated her work as "above average" and "very proficient."

The record reflects that petitioner has a history of medical problems predating her first hepatitis B vaccination. Between 1988 and 1994, Ms. Gardner-Cook visited a number of doctors for a variety of problems, including chest pain and tightness, difficulty breathing, depression and anxiety, fatigue, difficulty sleeping, persistent headaches, and dizziness. In the years prior to her first vaccination, petitioner was diagnosed with hypothyroidism, obesity, mitral valve prolapse,[1] anxiety, and depression.

On Friday, August 12, 1994, petitioner received her first hepatitis B vaccination at Lancaster General Hospital. According to the record, on August 15, 1994, petitioner visited her family physician, Dr. Gerstein, complaining of numbness in her left side. Petitioner was admitted to the hospital on August 15, 1994. While admitted, Ms. Gardner-Cook underwent a neurological consultation during which tests were conducted, including a CT scan (computed tomography) and MRI (magnetic resonance imaging). The results of both these tests revealed no brain abnormality. Ms. Gardner-Cook had a "positive Romberg," which was unexplained in the discharge records. The Romberg test is an equilibrium test that may reveal deficiencies in the manner in which position signals are sent to the brain.[2] Ms. Gardner-Cook was discharged from the hospital on August 17, 1994, and "was feeling almost back to normal," according to the discharge summary.

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[1] Mitral valve prolapse is defined as "excessive retrograde movement of one or both mitral valve leaflets into the left atrium [of the heart] during left ventricular systole [or contraction] ... ." Stedman's Medical Dictionary 1455 (27th ed. 2000).

[2] The Romberg sign is defined as follows:

> with feet approximated, the subject stands with eyes open and then closed; if closing the eyes increases the unsteadiness, a loss of proprioceptive control is indicated, and the sign is positive.

Stedman's Medical Dictionary 1640 (27th ed. 2000).

On September 9, 1994, petitioner received a second hepatitis B vaccination. Before the shot was administered, the record reflects that petitioner assured the nurse that there had been no problems with the first dose. On September 12, 1994, however, petitioner returned to her family physician, again complaining of numbness. The diagnosis was "[p]ossible serum sickness reaction to" the vaccine. Dr. Gerstein recommended "that she not complete the [vaccination] series because (A) it is making her sick" and (B) she was low-risk for contracting the virus. Over the course of the next several years, Ms. Gardner-Cook visited many specialists, including allergists, an immunologist, a rheumatologist, a pulmonologist, and a toxicologist, consistently complaining of numbness on her left side.

On December 12, 1995, Dr. Jack W. Snyder, a clinical toxicologist and associate professor in the Department of Emergency Medicine & Laboratory Medicine at Thomas Jefferson University, examined Ms. Gardner-Cook for a workmen's compensation claim she had filed. Dr. Snyder, who is board certified in toxicology, medical toxicology, toxicological chemistry, occupational medicine, and chemical pathology, determined that Ms. Gardner-Cook's symptoms were not attributable to the hepatitis B vaccinations. At the workmen's compensation claim hearing on September 9, 1996, Dr. Snyder testified that all of Ms. Gardner-Cook's reported post-vaccination symptoms can be explained by one or more of petitioner's preexisting medical conditions, namely, hypertension, sinusitis, bronchitis, drug allergies, depression, mitral valve prolapse, symptoms of colitis or excessive weight.

On July 23, 1999, petitioner filed a claim in the United States Court of Federal Claims seeking recovery under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to 300aa-34. Petitioner alleged that she experienced symptoms after each of the two administrations of the vaccine, "including neurologic symptoms indicative of a demyelinating disorder, which can leave long lasting neuropsychiatric deficits ... ." Significantly, petitioner alleged she suffered either Guillian-Barre Syndrome (GBS) or acute disseminated encephalomyelitis (ADEM) after the second vaccination. GBS and ADEM, similar to multiple sclerosis, are demyelinating[3] diseases affecting the nerve fibers in the nervous system. According to the respondent, however, the connection between hepatitis B vaccination and neurologic injury is largely unsupported in the medical literature.

In 2001, petitioner also was examined by Dr. Mark Kritchevsky, a professor of neurosciences at the Perlman Ambulatory Care Center, Behavorial Neurology Clinic, UCSD Healthcare. Dr. Kritchevsky wrote a detailed report, which is in the record, of his two hour examination of Ms. Gardner-Cook and review of her medical records. In his

[3] Demyelination is "[l]oss of myelin with preservation of the axons or fiber tracts" of the nerves. Stedman's Medical Dictionary 472 (27th ed. 2000). Myelin refers to a protein sheath that covers a nerve fiber. Id. at 1169.

report dated November 11, 2001, Dr. Kritchevsky concluded that Ms. Gardner-Cook probably had "functional somatic syndrome."[4] The report stated:

> I know of no good evidence that hepatitis B vaccine can lead to any serious or significant neurologic disorder. I do not believe that her neuropsychological testing shows "brain damage." Neither SPECT[5] nor PET[6] scan are reliable indicators of brain damage in a patient such as Ms. Gardner. Her baseline anxiety disorder made her more susceptible to the functional somatic syndrome from which she is suffering. The diagnosis of brain damage and the ongoing legal proceedings have likely contributed to symptom amplification and have also likely contributed to and worsened the functional somatic syndrome.

The special master conducted a hearing at the United States Court of Federal Claims in Washington, D.C. on July 19, 2002. At the hearing, petitioner offered Dr. Byron M. Hyde's expert testimony regarding petitioner's injuries. Ms. Gardner-Cook and her

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> The term *functional somatic syndrome* refers to several related syndromes that are characterized more by symptoms, suffering, and disability than by disease-specific, demonstrable abnormalities of structure or function. ... Patients with these syndromes often have very explicit disease attributions for their symptoms, and they resist information that contradicts these attributions. ... These patients often have a strong sense of assertiveness and embattled advocacy with respect to their etiologic suppositions, and they may devalue and dismiss medical authority and epidemiologic evidence that conflicts with their beliefs ... .

Arthur J. Barsky, M.D. & Jonathan F. Borus, M.D., "Functional Somatic Syndromes," 130 Annals Internal Med. 910 (1999) (emphasis in original), http://www.annals.org/issues/v130n11/full/199906010-00007.html.

5 Single photon emission computed tomography (SPECT) is defined as "tomographic imaging of metabolic and physiologic functions in tissues, the image being formed by computer synthesis of photons of a single energy emitted by radionuclides administered in suitable form to the patient." Stedman's Medical Dictionary 1842 (27th ed. 2000).

6 Positron emission tomography (PET) is defined as "creation of tomographic images revealing certain biochemical properties of tissue by computer analysis of positrons emitted when radioactively tagged substances are incorporated into the tissue." Stedman's Medical Dictionary 1842 (27th ed. 2000).

husband also testified regarding the course of her alleged illness and deterioration of her quality of life since the hepatitis B vaccinations.

Dr. Hyde is a self-described "investigative physician," as opposed to a "treating physician," who resides in Ottawa, Canada. Dr. Hyde testified at the July 19, 2002 hearing that he is the principal editor of a textbook on chronic fatigue syndrome and myalgic encephalomyelitis, but has not been board certified in any area. He practiced as a family practitioner for seventeen years until 1984, when he began studying certain "poorly defined" diseases, such as chronic fatigue syndrome. Currently, Dr. Hyde is not on staff or affiliated with any healthcare institution, but states that he is "basically lab and research oriented" and "self-funded" in his research on post-hepatitis B immunization patients. At the time of the hearing, Dr. Hyde was reviewing two other Vaccine Act cases, and had previously examined other post-hepatitis B vaccination patients in the United States and Canada. In Dr. Hyde's opinion, Ms. Gardner-Cook's symptoms indicated a disease similar to GBS and ADEM, but the information presented to him was insufficient to make an informed diagnosis of petitioner's specific illness. Dr. Hyde based his medical opinion on the results from the PET and SPECT scans of petitioner's brain, the positive Romberg, and a high level of ANA[7] detected in petitioner's blood.

At the hearing, respondent presented Dr. Kottil W. Rammohan, a neuroimmunologist and director of both the Multiple Sclerosis Center and the Neuroimmunology Laboratory at Ohio State University. Dr. Rammohan is board certified in internal medicine, neurology, and "neuro rehab," and was the first fellow in the Neuroimmunology Branch at the National Institute of Health in 1976. According to Dr. Rammohan, almost ninety percent of his patients have suspected immune disorders of the nervous system, such as multiple sclerosis, ADEM, lupus, or chronic infection. At the hearing before the special master, Dr. Rammohan testified that Ms. Gardner-Cook did not have ADEM, GBS, or any other demyelinating disorder. He attributed many of petitioner's symptoms to depression, which can cause cognitive decline. Dr. Rammohan testified that PET and SPECT scans are not generally used for diagnosis of GBS and ADEM. He also stated his opinion that the physicians performing the Romberg test probably performed or interpreted the tests incorrectly, since no other objective sign indicated neurological injury. Dr. Rammohan attributed petitioner's unusually high levels of ANA to the phenomenon of "biological false positive," induced by certain drugs. Regarding the positive ANA test results, Dr. Rammohan stated, "It's just a laboratory abnormality. ... We don't pay any attention to it if it isn't causing a clinical problem." In short, since petitioner had no

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[7] ANA, or antinuclear antibody, is defined as an antibody "showing an affinity for nuclear antigens including DNA and found in the serum of a high proportion of patients with systemic lupus erythematosus, rheumatoid arthritis, and certain collagen diseases, in some of their healthy relatives; also in about 1% of normal individuals." Stedman's Medical Dictionary 97 (27th ed. 2000).

objective signs of neurological injury, Dr. Rammohan concluded that she did not have ADEM, GBS, or any other neurological disorder caused by the hepatitis B vaccine.

The special master issued a decision on April 28, 2003, finding petitioner's expert's testimony not credible and dismissing the case with prejudice. The special master adopted Dr. Rammohan's conclusions regarding petitioner's medical condition and interpretation of her tests, as "supported in the record by the opinions of Dr. Jack W. Snyder, a toxicologist and Associate Professo[r] of Emergency Medicine, and Dr. Mark Kritchevsky, a Professor of Neurosciences." The special master found that Drs. Rammohan, Snyder, and Kritchevsky were "professionals capable of proffering appropriate opinions." Finally, the special master concluded:

> [P]etitioner has failed to prove a prima facie case that hepatitis B vaccine injured her neurologically or caused any illness whose sequelae lasted more than six months (as the statute requires: 42 U.S.C. § 300aa-11(c)(1)(D)). Ms. Gardner-Cook has had a hard life, filled with medical conditions (such as depression and obesity) which have led to many of her current problems. But she is not physically injured from the hepatitis B vaccination and, if as Dr. Rammohan testified, she had any injury at all, it did not last more than six months.

Gardner-Cook v. Sec'y DHHS, No. 99-480V (Fed. Cl. Spec. Mstr. Apr. 28, 2003).

Petitioner filed a timely motion for review of the special master's decision on May 28, 2003. Petitioner objects to the special master's findings "that the testimony of Petitioner was not credible;" "that Petitioner's expert, Byron M. Hyde, M.D., is not qualified to render an opinion in this case;" "that Petitioner did not have clinical symptoms and signs of a neurologic injury and was not injured neurologically;" "that Petitioner's arm and shoulder numbness began before the first vaccination;" and, finally, "that Petitioner failed to prove a prima facie case that Hepatitis B vaccine injured her neurologically." Before the court, petitioner asks that the decision of the special master be reversed and that judgment be entered in her favor.

DISCUSSION

When reviewing a special master's decision, the assigned judge of the United States Court of Federal Claims shall:

> (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 conclusions 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 conclusions 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); see also RCFC App. B, Rule 27. The legislative history of the Vaccine Act states that "[t]he 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. 386, 101st Cong., 1st Sess. 512-13, 517, reprinted in 1989 U.S.C.C.A.N. 1906, 3115, 3120.

Although this court's review of decisions issued by special masters under the Vaccine Act should be conducted within the bounds described above, 42 U.S.C. § 300aa-12(e)(2), case law dictates that the judges of this court should utilize differing and distinguishable standards of review, depending upon which aspect of the case is under scrutiny. As stated by the United States Court of Appeals for the Federal Circuit:

> These standards vary in application as well as degree of deference. Each standard applies to a different aspect of the judgment. Fact findings are reviewed by us, as by the Claims Court judge, under the arbitrary and capricious standard; legal questions under the "not in accordance with law" standard; and discretionary rulings under the abuse of discretion standard.

Saunders v. Sec'y DHHS, 25 F.3d 1031, 1033 (Fed. Cir. 1994) (quoting Munn v. Sec'y DHHS, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992)); see also Turner v. Sec'y DHHS, 268 F.3d 1334, 1337 (Fed. Cir. 2001); Tebcherani ex rel. Tebcherani v. Sec'y of DHHS, 55 Fed. Cl. 460, 472 (2003); Flanagan v. Sec'y DHHS, 48 Fed. Cl. 169, 173 (2000), aff'd sub nom. Turner v. Sec'y DHHS, 268 F.3d 1334 (2001); Grice v. Sec'y DHHS, 36 Fed. Cl. 114, 117 (1996); Rooks v. Sec'y DHHS, 35 Fed. Cl. 1, 4 (1996); Cox v. Sec'y DHHS, 30 Fed. Cl. 136, 142 (1993); Perreira v. Sec'y DHHS, 27 Fed. Cl. 29, 32 (1992), aff'd, 33 F.3d 1375 (Fed. Cir. 1994). The abuse of discretion standard will rarely come into play except, for example, when the special master excludes evidence. Munn v. Sec'y DHHS, 970 F.2d at 870 n.10.

The arbitrary and capricious standard of review is a narrow one. Rupert ex rel. Rupert v. Sec'y DHHS, 55 Fed. Cl. 293, 297 (2003) (citing Carraggio v. Sec'y DHHS, 38 Fed. Cl. 211, 217 (1997)); Johnston v. Sec'y DHHS, 22 Cl. Ct. 75, 76 (1990); see Lampe v. Sec'y DHHS, 219 F.3d 1357, 1360 (Fed. Cir. 2000); Cucuras v. Sec'y DHHS, 993 F.2d 1525, 1527 (Fed. Cir. 1993); Bradley v. Sec'y DHHS, 991 F.2d 1570, 1574 (Fed. Cir. 1993); Beddingfield v. Sec'y DHHS, 50 Fed. Cl. 520, 523 (2001); Fadelalla v. United

States, 45 Fed. Cl. 196, 198 (1999); Estate of Arrowood v. Sec'y DHHS, 28 Fed. Cl. 453, 457 (1993); Perreira v. Sec'y DHHS, 27 Fed. Cl. at 31-32; see also Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). The United States Court of Appeals for the Federal Circuit also has defined the arbitrary and capricious standard of review as "highly deferential." Burns v. Sec'y DHHS, 3 F.3d 415, 416 (Fed. Cir. 1993) (citing Hines v. Sec'y DHHS, 940 F.2d 1518, 1528 (Fed. Cir. 1991)); see also Turner v. Sec'y DHHS, 268 F.3d at 1339; Munn v. Sec'y DHHS, 970 F.2d at 869; Tebcherani ex rel. Tebcherani v. Sec'y of DHHS, 55 Fed. Cl. at 473 (citing Gurr v. Sec'y of HHS, 37 Fed. Cl. 314, 317 (1997)); Camery v. Sec'y DHHS, 42 Fed. Cl. 381, 385 (1998). When applying the arbitrary and capricious standard, a reviewing court is not empowered to substitute its own judgment for that of a previous trier of fact. Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. at 416; see also Tebcherani ex rel. Tebcherani v. Sec'y of DHHS, 55 Fed. Cl. at 480 ("The Special Master is responsible for weighing the testimony and other evidence and drawing reasonable inferences. This court does not substitute its own judgment for that of that Special Master when he has considered and weighed the evidence.") (citations omitted); accord Terran v. Sec'y DHHS, 195 F.3d 1302, 1316 (Fed. Cir. 1999), cert. denied sub nom. Terran v. Shalala, 531 U.S. 812 (2000); Fadelalla v. United States, 45 Fed. Cl. at 198-99. Instead, when determining whether a decision was arbitrary and capricious, a court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. at 416; see also Hines v. Sec'y DHHS, 940 F.2d at 1527.

Furthermore, "[i]f the special master has considered the relevant evidence in the record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Burns v. Sec'y DHHS, 3 F.3d at 416; see also Lampe v. Sec'y DHHS, 219 F.3d at 1360; Hines v. Sec'y DHHS, 940 F.2d at 1528; Beddingfield v. Sec'y DHHS, 50 Fed. Cl. at 523; Turner v. Sec'y DHHS, 48 Fed. Cl. 243, 246 (2000), aff'd, 268 F.3d 1334 (Fed. Cir. 2001); Fadelalla v. United States, 45 Fed. Cl. at 198-99; Lewis v. Sec'y DHHS, 26 Cl. Ct. 233, 236 (1992); Murphy v. Sec'y DHHS, 23 Cl. Ct. 726, 729-30 (1991), aff'd, 968 F.2d 1226 (Fed. Cir. 1992), cert. denied, 506 U.S. 974 (1992). Thus, the decision of a special master may be found to be arbitrary and capricious only if the special master:

> relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence ... or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Hines v. Sec'y DHHS, 940 F.2d at 1527 (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983)); see also Lampe v. Sec'y DHHS, 219 F.3d at 1360.

The "'not in accordance with law' standard" which applies to legal questions, warrants de novo review. Neher by Neher v. Sec'y DHHS, 984 F.2d 1195, 1198 (Fed. Cir. 1993); Bradley v. Sec'y DHHS, 991 F.2d at 1574 n.3; Munn v. Sec'y DHHS, 970 F.2d at 870 n.10. Judicial review of legal issues must result in a conclusion by the decision maker that the legally controlling directive involved, such as a statute or regulation, either does or does not permit the action under review. Therefore, review of legal conclusions is not a question of weighing the evidence and deference is not at issue.

The Vaccine Act provides an alternative to the traditional tort system for individuals who have suffered vaccine-related injuries. See Lowry ex rel. Lowry v. Sec'y DHHS, 189 F.3d 1378, 1381 (Fed. Cir. 1999); Whitecotton v. Sec'y DHHS, 81 F.3d 1099, 1102 (Fed. Cir. 1996); reh'g denied (1996). Under the Vaccine Act, a petitioner who has received a vaccination listed on the Vaccine Injury Table (Table) may recover for an associated illness, disability, injury or condition also listed on the Table. See 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3. Under this "on-Table" theory of recovery, the Vaccine Act also entitles a petitioner to compensation if he or she suffers significant aggravation[8] of a pre-existing Table injury. 42 U.S.C. §§ 300aa-11(c)(1)(C)(i), 300aa-14(a); Whitecotton v. Sec'y DHHS, 81 F.3d at 1102. Congress provided for such cases

> in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis).

Whitecotton v. Sec'y DHHS, 81 F.3d at 1102-03 (quoting H.R. Rep. No. 99-908, at 1, reprinted in 1986 U.S.C.C.A.N. 6287, 6356). Petitioner also must show that the first symptom or manifestation of the significant aggravation of a Table injury occurred within the time period set forth on the Table. 42 U.S.C. § 300aa-11(c)(1)(C)(i); Whitecotton v. Sec'y DHHS, 81 F.3d at 1103. Therefore, under the "on-Table" theory of recovery, if petitioner shows (1) that he or she experienced an illness, disability, injury, or condition recognized by the Table and (2) that the first symptom or manifestation of his or her illness, disability, injury or condition occurred within the time period listed on the Table, causation is presumed and petitioner is considered to have made out a prima facie case of entitlement to compensation. See 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3. Still, "the government may ... rebut the presumption of an on-Table injury by showing that the injury

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[8] The Vaccine Act states that "[t]he term 'significant aggravation' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4).

complained of resulted from some factor unrelated to the disease." Turner v. Sec'y DHHS, 268 F.3d at 1337; see 42 U.S.C. § 300aa-13(a)(1)(B).

A petitioner who has been administered a vaccination that is listed on the Table, but whose vaccine-related injuries do not meet the Table requirements, may recover under the "off-Table" theory of recovery. See 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A). Under the "off-Table" theory, a petitioner may make out a prima facie case of entitlement to compensation upon a showing by a preponderance of the evidence that a Table vaccine actually caused petitioner to sustain an illness, disability, injury or condition that is not recognized on the Table, or that first appeared outside the given time periods on the Table. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii). Thus, "[t]he Act relaxes proof of causation for injuries satisfying the Table in § 300aa-14, but does not relax proof of causation in fact for non-Table injuries." Grant v. Sec'y DHHS, 956 F.2d 1144, 1148 (1992). Petitioner's burden of proof under the off-Table theory of recovery is a heavy one. Whitecotton v. Sec'y DHHS, 81 F.3d at 1102. "To prove causation in fact, petitioners must show a medical theory causally connecting the vaccination and the injury." Grant v. Sec'y DHHS, 956 F.2d at 1148.

Petitioner claims that, as a result of two hepatitis B vaccinations administered in 1994, she is entitled to compensation for an off-Table injury, with conditions and symptoms not listed on the Vaccine Injury Table. Under the off-Table theory of recovery, petitioner is entitled to compensation if she can demonstrate by a preponderance of the evidence (42 U.S.C. § 300aa-13(a)(1)(A)) that she "sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table [42 U.S.C. § 300aa-14(a) and 42 C.F.R. § 100.3] but which was caused by a vaccine" that is listed on the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Thus, under the off-Table theory of recovery, petitioner may recover for an injury not listed on the Vaccine Injury Table if the injury was caused by a vaccine that Congress has recognized on the Table, or that was added by the Secretary of Health and Human Services, who may promulgate regulations to modify the Vaccine Injury Table. See 42 U.S.C. § 300aa-14(c)(1). Hepatitis B vaccination, although not listed in the "Initial table" found at 42 U.S.C. § 300aa-14(a), was listed on the Vaccine Injury Table as of August 6, 1997. See 42 C.F.R. § 100.3(c)(2). Since plaintiff's condition does not meet the requirements of a presumptively vaccine-related condition, in order to prove eligibility for compensation for an off-Table injury under the Vaccine Act, petitioner may not rely on her testimony alone, but must present medical records or a medical opinion to support her theory of injury. See 42 U.S.C. § 300aa-13(a)(1) ("The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.") Accordingly, the burden is on the petitioner to prove her claim through medical records and/or credible medical, expert testimony.

On April 28, 2003, the special master issued a decision dismissing petitioner's claim for compensation for an off-Table injury caused by hepatitis B vaccine. The special master based her dismissal of petitioner's claim, in large part, on the testimony of Dr. Rammohan, as supported by other experts whose opinions were presented to the court as part of the record. On May 28, 2003, petitioner filed a motion for review of the special master's decision in the United States Court of Federal Claims. Petitioner objects to the special master's findings that she was not injured by the hepatitis B vaccinations; that Dr. Hyde and Ms. Gardner-Cook were not credible witnesses, while accepting the medical opinion of Dr. Rammohan;[9] that petitioner was not injured neurologically; and that petitioner's left side numbness appeared before the first vaccination.

The special master in a vaccine case is charged under the statute with issuing an opinion which shall "include findings of fact and conclusions of law." 42 U.S.C. § 300aa-12(d)(3)(A)(i). "Determining the weight and credibility of the evidence is the special province of the trier of fact." Inwood Lab., Inc. v. Ives Lab., Inc., 456 U.S. 844, 856 (1982);

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[9] The special master also determined that Ms. Gardner-Cook's testimony was not credible because she denied any pre-vaccination history of depression, when her medical records reflect six instances of depression from 1989 through 1993. Ms. Gardner-Cook denied any depression except an episode of postpartum depression after her daughter was born. This apparent disparity between Ms. Gardner-Cook's testimony and her medical records serves as a reasonable basis for the special master's determination regarding petitioner's lack of credibility, such that the finding was not arbitrary or capricious. According to petitioner's Memorandum of Objections, however, Ms. Gardner-Cook "felt her doctor visits were about anxiety and panic disorder, not depression." In her testimony, Ms. Gardner-Cook admitted to a pre-vaccination history of anxiety and panic disorder, but went on to explain, "Well, the only time I consider myself as having any type of depression was postpartum with [my daughter]. I've never considered myself, you know, depressed. I'm not the type that, you know, would want to lay in bed. I'm the type who does a lot of things." When cross-examined about a history of pre-vaccination depression, Ms. Gardner-Cook added:

> Well, I get really upset when people say depression because I don't consider myself a depressed person. ... I had postpartum depression with my daughter, but it wasn't like – what is it – clinical depression. I have anxiety disorder. My father had it. All my siblings have it. I have it. It's totally different than being depressed. It's just panic. It's not wanting to lay in bed and not do anything.

Regardless of whether the petitioner intended to mislead the court regarding her pre-vaccination medical history, the special master's dismissal of petitioner's claim is reasonably documented and supported in the record, even accepting the testimony of Ms. Gardner-Cook.

see Tebcherani ex rel. Tebcherani v. Sec'y DHHS, 55 Fed. Cl. 460 at 480 ("This court does not substitute its own judgment for that of the Special Master when he [or she] has considered and weighed the evidence presented."); Raspberry v. Sec'y DHHS, 33 Fed. Cl. 420, 423 (1995). Thus, the special master was free to accept or reject portions of the expert medical opinions presented to her in light of the entire record. See Munn v. Sec'y DHHS, 21 Cl. Ct. 345, 350 (1990), aff'd, 970 F.2d 863 (Fed. Cir. 1992); see also Wittner ex rel. Wittner v. Sec'y DHHS, 43 Fed. Cl. 199, 208 (1999); Mills v. Sec'y DHHS, 27 Fed. Cl. 573, 578 (1993). It is important to remember that "[t]he fact-finder has broad discretion in determining credibility because he [or she] saw the witnesses and heard the testimony." Bradley v. Sec'y DHHS, 991 F.2d 1570, 1575 (Fed Cir. 1993). It is well-established that witness credibility is primarily within the purview of the trier of fact, and that a special master's determinations of credibility should be given appropriate deference because he or she had the opportunity to listen to the testimony, ask questions of the witnesses, and observe their demeanor. Griessenauer v. Dep't of Energy, 754 F.2d 361, 364 (Fed. Cir. 1985); Camery v. Sec'y DHHS, 42 Fed. Cl. at 390 (quoting Bradley v. Sec'y DHHS, 991 F.2d at 1575); Richardson v. Sec'y DHHS, 23 Cl. Ct. 674, 678 (1991); see also Burns v. Sec'y DHHS, 3 F.3d at 417; Snyder by Snyder v. Sec'y DHHS, 36 Fed. Cl. 461, 465 (1996), aff'd 117 F.3d 545 (1997); Horner v. Sec'y DHHS, 35 Fed. Cl. 23, 28 (1996). This court should not second-guess the credibility determinations of the special master unless they are proven to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. A special master's determinations regarding credibility are "virtually unreviewable." See also Bradley v. Sec'y DHHS, 991 F.2d at 1575 (citing Hambsch v. Dep't of Treasury, 796 F.2d 430, 436 (Fed. Cir. 1986)); Tebcherani ex rel. Tebcherani v. Sec'y DHHS, 55 Fed. Cl. at 480; Snyder by Snyder v. Sec'y DHHS, 36 Fed. Cl. at However, "consistent medical records are given weight over conflicting testimony offered after the fact." Camery v. Sec'y DHHS, 42 Fed. Cl. at 390.

Dr. Hyde, petitioner's expert witness, testified that Ms. Gardner-Cook suffered from a demyelinating disease like ADEM or GBS that was caused by the hepatitis B vaccinations. However, the special master found that "Dr. Hyde's testimony strongly suggests that he is alone against the mainstream of the medical establishment. ... It may well be that hepatitis B vaccine causes adverse reactions, but Dr. Hyde's opinion in this case is highly suspect and not credible." This credibility determination by the special master was based on several factors. Dr. Hyde had not practiced medicine since 1984, and never practiced neurology or neuroimmunology. Dr. Hyde, himself, testified that Ms. Gardner-Cook should have been examined by a neuroimmunologist, which Dr. Hyde is not. According to the special master, Dr. Hyde made statements regarding petitioner's alleged demyelination that "seem[ed] contrary to accepted medical knowledge,"[10] and his medical opinion appeared to be based largely on the apparent association of Ms. Gardener-Cook's

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[10]Specifically, Dr. Hyde suggested petitioner could experience serious demyelination which could remain undetected by present technology, a statement that the special master found contrary to accepted medical knowledge.

left side numbness and the vaccinations, while ignoring other pre-vaccination symptoms. In sum, the special master found that Dr. Hyde's "medical skills are limited, his opinion is outside contemporary medical opinion ... and he is tainted by a bias toward finding a causative nexus regardless of the facts of the individual case. He is unqualified to give an opinion here."

By contrast, the special master found Dr. Rammohan, respondent's expert witness, "capable of proffering appropriate opinions ... knowledgeable about neuroimmunology and totally credible." Dr. Rammohan testified that Ms. Gardner-Cook did not have ADEM, GBS, or any other demyelinating disease caused by the hepatitis B vaccination. The special master's credibility assessment is supported in a number of ways. Dr. Rammohan is a specialist in demyelinating diseases. He has a clinical practice, does research, and is board-certified in internal medicine, neurology, and "neuro rehab." Further, Dr. Rammohan's testimony was supported by the opinions of other experts in the fields of toxicology and neurosciences, Drs. Snyder and Kritchevsky, whose medical opinions also were submitted to the special master and made part of the record. For these reasons, the special master found that Dr. Rammohan's interpretation of petitioner's symptoms was credible and endorsed the position of the respondent regarding petitioner's claims.

Petitioner objects to the special master's finding that she did not establish a prima facie case that hepatitis B vaccination caused her an injury that is compensable under the Vaccine Act. The United States Court of Appeals for the Federal Circuit addressed the evidentiary burden under the Vaccine Act for recovery for an off-Table injury in Shyface v. Sec'y DHHS, 165 F.3d 1344 (Fed. Cir. 1999). The Federal Circuit held that:

> establishment of prima facie entitlement to compensation according to the non-Table method would require the petitioner to prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury. As discussed in Grant [v. Sec'y DHHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992)], in order to show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show "a medical theory causally connecting the vaccination and the injury." There must be a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Id.

Id. at 1352-53. Therefore, an actual causation, or off-Table injury, claim must be supported by a logical sequence of cause and effect proving that the vaccination was the reason for the injury. See Hodges v. Sec'y DHHS, 9 F.3d 958, 961 (Fed. Cir. 1993). "[A] proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." Grant v. Sec'y DHHS, 956 F.2d at 1148; see also Keith v. Sec'y DHHS, 55 Fed. Cl. 791, 798 (2003); Wittner v. Sec'y DHHS, 43 Fed. Cl. at 207. Moreover, "[a] reputable medical or scientific explanation must support this logical sequence of cause and effect." Id. (citations omitted); see also Jay v. Sec'y DHHS, 998

F.2d 979, 984 (Fed. Cir.) reh'g denied (1993); Grant v. Sec'y DHHS, 956 F.2d at 1148; Keith v. Sec'y DHHS, 55 Fed. Cl. at 798 (2003). In addition, in order to be eligible for compensation, the petitioner must have

> (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention ... .

42 U.S.C. § 300aa-11(c)(1)(D).

Petitioner alleged that she experienced severe neurologic symptoms which appeared after the vaccinations. In her Memorandum of Objections, petitioner notes that three physicians, after reviewing Ms. Gardner-Cook's medical symptoms, suggested petitioner's symptoms might indicate a demyelinating disorder. In response to petitioner's normal brain scans, petitioner's Memorandum of Objections asserts that her anatomical defects "are too small to be detected on MRI but may be observed upon autopsy." Accordingly, petitioner maintains that she was injured neurologically by the two hepatitis B vaccinations, and requests that this court reverse the judgment of the special master and enter judgment in her favor.[11]

Respondent notes that, in order for petitioner to meet her burden of proving an off-Table injury under the Vaccine Act, petitioner must support her causation theory with the opinion of a valid medical expert. According to respondent, because the special master appropriately rejected the testimony of petitioner's expert, Dr. Hyde, petitioner has not met her burden of showing actual causation in this case.

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[11] Petitioner's Memorandum of Objections makes no mention of the appropriate standard of review in this court. As respondent's Memorandum in Response to Petitioner's Motion for Review correctly states: "In view of the deferential standard of review, the only legitimate question on appeal is whether there exists any rational basis for the special master's decision." Petitioner's Memorandum instead asserts, "The sole issue in this case is whether, based on the record evidence as a whole and the totality of the case, it has been shown by a preponderance of the evidence that the vaccine caused Petitioner's injury." In requesting that this court reverse the judgment of the special master, petitioner adds "that the Respondent's position is supported neither by current medical literature nor by reason. It is submitted the learned Special Master erred in failing to consider all the evidence as a whole." Neither of these statements correctly articulates the appropriate standard of review in this court. As discussed above, the Vaccine Act and case law establish a "highly deferential" standard for this court's review of the special master's factual findings.

As addressed above, the special master found that petitioner's expert, Dr. Hyde, was not a professional capable of offering an expert opinion on an alleged neuroimmunological disorder, and discredited his testimony that petitioner suffered from a demyelinating disorder, similar to ADEM or GBS, caused by the hepatitis B vaccinations. Moreover, petitioner's medical records did not present conclusive evidence of a neurological disorder. Without the expert opinion of Dr. Hyde and support of medical documents, petitioner is left only with the claimed temporal association of her alleged neurological symptoms and the hepatitis B vaccinations.[12] "Temporal association is not sufficient, however, to establish causation in fact." Grant v. Sec'y DHHS, 956 F.2d at 1148. Therefore, the special master found that petitioner failed to establish a logical sequence of cause and effect, supported by a valid, medical, expert opinion, sufficient to connect the vaccination to petitioner's reported neurological injuries.

This court should not re-weigh the evidence presented to the special master, or substitute its own judgment for that of the trier of fact. See 42 U.S.C. § 300aa-12(e)(2); Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. at 416. The arbitrary and capricious standard of review is highly deferential to the findings of the special master. Turner v. Sec'y DHHS, 268 F.3d at 1339; Munn v. Sec'y DHHS, 970 F.2d at 869; Tebcherani ex rel. Tebcherani v. Sec'y DHHS, 55 Fed. Cl. at 474; Camery v. Sec'y DHHS, 42 Fed. Cl. at 387. "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." Burns v. Sec'y DHHS, 3 F.3d at 416. The special master's credibility determinations were reasonable, and were, therefore, not arbitrary or capricious. In the absence of a valid medical opinion supporting a logical sequence of cause and effect to explain petitioner's alleged injury, the special master

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[12] In fact, the special master found the petitioner's numbness symptoms began before the hepatitis B vaccinations were ever administered, a finding to which petitioner objects. The petitioner disputes the special master's finding of preexisting numbness, citing to evidence in the record of her descriptions to doctors of when the numbness began. The special master apparently considered a nurse's note, dated August 12, 1994, that was submitted as part of petitioner's medical records, and concluded that petitioner's numbness appeared the weekend prior to the first vaccination. Petitioner asserts that the date on the nurse's note was incorrect. According to the petitioner, instead of August 12, 1994, which is the day of the first vaccination, the date on the nurse's note should have read August 15, which is the same day as Dr. Gerstein's note in the record and the same day that Ms. Gardner-Cook was admitted to Lancaster General Hospital. The special master, however, cited further evidence of pre-vaccination numbness, including a letter sent by petitioner in 1989 in which she complained of numbness in her arms and legs. Even taking into account conflicting evidence, the special master had a reasonable basis for the finding that petitioner's left side numbness appeared before the first hepatitis B vaccination on August 12, 1994. Therefore, the special master's determination in this regard was not arbitrary and capricious.

reasonably concluded that petitioner did not present a prima facie case of vaccine injury. Petitioner's burden in this court is a difficult one to satisfy, and petitioner in this case has not met her burden of proving the special master's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

CONCLUSION

Based upon a review of the opinion of the special master, and the testimony, exhibits, and submissions in this case, the court upholds the findings of fact and conclusions of law of the special master. The Clerk of the Court is instructed to enter judgment in accordance with this opinion.

IT IS SO ORDERED.

MARIAN BLANK HORN
Judge