# In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 07-283V
November 21, 2007
To be Published

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| MATTHEW WIECHART and JUSTIN WIECHART, as the Legal Representatives of their minor son, KEITH WIECHART, | * | |
| Petitioners, | * | |
| v. | * | Entitlement; no proof of causation in fact; assertion that current definition of Table acute encephalopathy should be scrapped and previous definition used legally invalid |
| SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |

Curtis R. Webb, Twin Falls, ID, for petitioners.
Lisa A. Watts, Washington, DC, for respondent.

**MILLMAN, Special Master**

## DECISION[1]

Petitioners filed a petition on May 4, 2007, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that acellular DPT administered to their son Keith

[1] Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Wiechart (hereinafter, "Keith") significantly aggravated his pre-existing infantile spasms which began earlier in March or April 2004.

On June 1, 2007, the undersigned held the first status conference with the parties during which petitioners' counsel stated that the current definition of a Table acute encephalopathy for all petitions filed on or after March 10, 1995 cannot be applied to significant aggravation cases of a preexisting encephalopathy, and, therefore, the initial definition of a Table encephalopathy in the qualifications and aids to interpretation (QAIs) should instead apply.

After seeking and obtaining a 30-day extension of time, petitioners filed, on September 6, 2007, a Memorandum entitled The Definition of Encephalopathy to Apply to Keith Wiechart's Preexisting Condition. On page 2 of their Memorandum, petitioners state that Keith's condition prior to his acellular DPT vaccination "may" satisfy the definition of the original Table encephalopathy before the 1995 change, citing 42 U.S.C. § 300aa-14(b)(3)(A). Petitioners admit that Keith's prevaccination condition "clearly does not satisfy the definition of 'encephalopathy' in current regulations governing the Vaccine Injury Table. 42 CFR § 100.3(b)(2), 62 Fed. Reg. 7685 (Feb. 20, 1997)." *Id.*

On page 3 of their Memorandum, petitioners state that they "do not believe that they can prove" that Keith's acellular DPT vaccination caused in fact the worsening of his condition. They ask the undersigned to apply the prior definition of a Table encephalopathy because a literal application of the current definition of a Table acute encephalopathy "would lead to an absurd result: it would preclude all Program claims based on the significant aggravation of a Table encephalopathy." *Id.*

The reason for petitioners' claim that the current definition of a Table acute encephalopathy as applied to a significant aggravation of a preexisting encephalopathy would lead to an absurd result is that the encephalopathy would have to occur within three days of a DPT or acellular DPT vaccination or within 5 to 15 days after a MMR vaccination, which the regulation refers to as "within the applicable period." The current QAI also requires that an acute encephalopathy be followed by a chronic encephalopathy lasting more than six months. Memorandum at 3, 4, 5. Petitioners argue that someone whose encephalopathy arose before vaccination and within six months of vaccination could never satisfy the QAI definition of an acute encephalopathy in order to prove a Table significant aggravation of encephalopathy case.

Petitioners cite the chief special master's decision in DeRoche v. Secretary of HHS, No. 97-643V, 2002 WL 603087 (Fed. Cl. Spec. Mstr. Mar. 28, 2002), in which pro se petitioners made the same argument. The chief special master's response was not to refuse to apply the current regulation, but to eliminate the requirement that: (1) the preexisting encephalopathy occurred within an applicable period after a vaccination, and (2) a chronic encephalopathy followed the acute encephalopathy for more than six months. The chief special master did not declare the definition unusable. *Id.* at 29. He rejected as unacceptable petitioners' proposal to reject the revised definition's application because it would leave petitioners without any encephalopathy definition. *Id.* at n.61. Petitioners' argument and proposal in DeRoche are petitioners' argument and proposal here.

On page 8 of their Memorandum, petitioners suggest that the undersigned use the original statutory definition of encephalopathy as a remedy for the imperfections of the current definition in the QAIs. Petitioners did not believe that the chief special master's approach in DeRoche

made any sense. *Id.* at 9. Their reason is that the chief special master's approach would require petitioners herein to prove that Keith had an acute encephalopathy involving a significantly decreased level of consciousness before his vaccine-related injury in order to pursue a Table significant aggravation case. *Id.* They then cite to the definition of significant aggravation as expressed in the Vaccine Act which refers to the significant aggravation of seizures. (Seizures were previously Table injuries.) *Id.*

On page 10, petitioners state there is no "rational" reason for them to have to prove that Keith had a preexisting acute encephalopathy or a significantly decreased level of consciousness for them to win a Table significant aggravation of a preexisting encephalopathy case. They then refer to the pre-March 10, 1995 definition of a Table encephalopathy as if it would ensure Keith's recovery of damages in this case. *Id.* They omit mentioning that the pre-March 10, 1995 definition of a Table encephalopathy included a change in the level of consciousness lasting at least six hours. They ask the undersigned to apply the pre-March 10, 1995 definition of a Table encephalopathy to this case. *Id.*

On September 7, 2007, the undersigned issued an Order asking petitioners to consider that there was no evidence in the record that Keith had an acute encephalopathy before his May 5, 2004 acellular DPT vaccination. In between Keith's infantile spasms, the medical records showed Keith was normal and developing normally, as petitioners stated on page 2 of their Memorandum. Because Keith did not have a significantly decreased level of consciousness lasting at least six hours, the undersigned doubted that petitioners would benefit from the undersigned's using the pre-March 10, 1995 definition of a Table encephalopathy assuming arguendo the undersigned thought the current definition of a Table acute encephalopathy was

unworkable even in light of the chief special master's adapting it in DeRoche to fit Table significant aggravation of preexisting encephalopathy cases.

The undersigned also questioned, at page 2 of the Order, petitioners' assumption that the undersigned was empowered to ignore regulations which have the force of law. When Congress permitted the Secretary of the Department of Health and Human Services to promulgate regulations that would substitute a new Vaccine Injury Table for the old Table, 42 U.S.C. § 300aa-14(c)(1), (3), and (4), Congress bound the special masters to execute these regulations just as much as they were bound to execute the original Vaccine Injury Table. The promulgated regulations affect all petitions filed after the effective date of each regulation. *Id.* at (4).

The undersigned concluded that the chief special master's solution in DeRoche to eliminate the reference to "within the applicable period" and the requirement of a six-month chronic encephalopathy following the acute encephalopathy was appropriate and enabled the undersigned to enforce the regulation without irrationality or absurdity as applied to Table significant aggravation cases of preexisting encephalopathy. The undersigned stated that Keith did not have an acute encephalopathy under either the old or new definitions of a Table encephalopathy.

On September 13, 2007, petitioners filed a Response to Special Master's September 7, 2007 Order, conceding that Keith did not suffer an acute encephalopathy before or after his May 5, 2004 acellular DPT vaccination. *Id.* at 1. They stated that if the undersigned applied either the current Table definition of encephalopathy or the chief special master's resolution in DeRoche, the undersigned should dismiss petitioners' case. *Id.* However, petitioners asserted at page 2 of their Response that the original definition of a Table encephalopathy did not require that the

encephalopathy be acute, underlining the first sentence of the 5-sentence definition, to wit, "The term 'encephalopathy' means any significant acquired abnormality of, or injury to, or impairment of function of the brain." They do not discuss the other four sentences of the definition.

On September 25, 2007, respondent filed a Response to Petitioners' Memorandum That the Current Regulatory Definition of Encephalopathy Should Not Apply to Their Claim of Significant Aggravation Under the Vaccine Injury Table. Respondent notes that the medical records for Keith's six-month well baby visit on May 5, 2004 reveals that Keith's mother reported approximately one month earlier, Keith began rolling his eyes and losing control of his head. P. Ex. 3B, p. 26. Developmentally, Keith laughed, babbled, sat with support, bore some weight, and turned to sound. *Id.* His neurological examination was normal. *Id.* Respondent at p. 4 of the Response cites the Federal Circuit's decision in Terran v. Secretary of HHS, 195 F.3d 1302, 1308 (Fed. Cir. 1999), which states that "the Act provides that if the Initial Table is modified, the original QAIs cease to apply unless the modified Table expressly states that they remain valid."

Respondent notes at page 5 of the Response that petitioners concede they cannot prove Keith had an acute encephalopathy prior to his acellular DPT vaccination. Petitioners also concede they cannot prove causation in fact. *Id.* at 6. Respondent states that the undersigned cannot ignore the Vaccine Injury Table and QAI, citing the Federal Circuit in Althen v. Secretary of HHS, 418 F.3d 1274, 1280 (Fed. Cir. 2005), that the "special master's role is to apply the law."

On November 8, 2007, petitioners filed a Reply Memorandum, reiterating that the undersigned cannot rationally apply 42 CFR § 100.3(b)(2) to an allegation of a Table significant

aggravation of a preexisting encephalopathy case. *Id.* at 1. They state at page 3 that the statute and the regulation cannot be reconciled. They do not accept the chief special master's resolution of the regulatory language difficulty in DeRoche. *Id.* at 3. They do not think the Secretary of HHS ever considered significant aggravation of preexisting encephalopathy cases in revising the definition of a Table encephalopathy. *Id.* at 4.

**DISCUSSION**

The prior definition of a Table encephalopathy, 42 U.S.C. § 300aa-14(b)(3)(A), was:

> The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

The current definition of a Table encephalopathy, promulgated on February 8, 1995, effective March 10, 1995, 42 CFR § 100.3(b)(2), is:

> For purposes of paragraph (a) [the Vaccine Injury Table] of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such a person for more than 6 months beyond the date of vaccination.

Because Keith was less than 18 months of age and had had seizures, the second part of subparagraph (A) would apply to him, requiring a "significantly decreased level of consciousness

[that] persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication."

Subsection (D) defines a "significantly decreased level of consciousness" as "indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater...:"

> (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
> (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
> (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

Subsection (E) states, inter alia: "Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy."

The Federal Circuit in Terran states at 195 F.3d at 1308:

> Congress intended the Secretary [of HHS] to revise and update the Initial Table with more accurate information that would become available as a result of the research on vaccine injuries mandated by the Vaccine Act. *See* National Childhood Vaccine Injury Act of 1986, Pub.L. No. 99-660, § 312, 1986 U.S.C.C.A.N. (100 Stat.) 3755, 3779-81 (requiring the Secretary to make findings on the accuracy of the Initial Table with respect to, *inter alia*, pertussis vaccines and to propose regulations to modify the Initial Table accordingly); H.R. Rep. No. 99-908, at 18, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6359. Thus, the Vaccine Act gives the Secretary the express power to promulgate regulations that modify the Table by adding to, or deleting from, the list of compensable disorders and by revising the time periods contained in the Table. *See* 42 U.S.C. § 300aa-14(c)(3)(1994).

Most importantly, for purposes of the discussion in this case, the Federal Circuit states:

> In addition, the Act provides that if the Initial Table is modified, the original QAIs cease to apply unless the modified Table expressly states that they remain valid.

*Id.* The revised definition of encephalopathy does not state that the original definition of encephalopathy remains valid. The Federal Circuit comments that 1995 Table and associated QAI "significantly narrowed the definition of 'encephalopathy.'" *Id.*

The Federal Circuit in Terran also states that the Secretary had promulgated "an entirely new vaccine injury table." *Id.* at 1312. The Federal Circuit concludes from this point that:

> Congress therefore clearly intended that the Initial Table would cease to apply to newly filed petitions when the Secretary promulgated a revised injury table. *See id.* § 300aa-14(c)(4). This aspect of the Vaccine Act is similar to "sunset" provisions that Congress routinely includes in legislation to specify the date on which a particular piece of legislation ceases to have effect.

*Id.* at 1313.

The Federal Circuit adds that "the Secretary's promulgation of a revised injury table triggers the ineffectiveness of the Initial Table." *Id.* The Federal Circuit also states that "the Secretary was executing congressional policy when she promulgated the 1995 Table. Indeed, the Act explicitly directed the Secretary to study pertussis vaccines and to promptly promulgate a revised injury table based on such findings." *Id.* at 1314.

The Secretary's regulations bind the undersigned since they have legislative effect. INS v. Chadha, 462 U.S. 919, 986 (1983). The United States Supreme Court also stated that statutes must be construed in the light of their purpose. An absurd result must be avoided by giving them a reasonable application consistent with their words and with the legislative purpose. Haggar Co. v. Helvering, 308 U.S. 389, 394 (1940); Hellebrand v. Secretary of HHS, 999 F.2d 1565, 1571-

72 (Fed. Cir. 1993). The Secretary's purpose as the Federal Circuit stated in Terran was to narrow significantly the definition of a Table encephalopathy. The Federal Circuit also stated in Terran that the original Table definition of encephalopathy is ineffective and ceases to apply to petitions, such as this one, filed after the effective date of the regulation.

The undersigned concludes that petitioners' proposal and argument are not legally sound and that the undersigned cannot legally revert to the original definition of a Table encephalopathy because it ceased to apply to petitions filed after March 10, 1995, and does not conform with congressional intent that the Secretary of HHS promulgate statutory changes in conformance with the study of vaccines, particularly pertussis vaccines. The DeRoche solution satisfies the quandary in the current regulation as applied to Table significant aggravation cases.

Because petitioners state they cannot make a Table case of significant aggravation under the current definition of encephalopathy and they cannot prove a causation in fact case, they have failed to make a prima facie case and the undersigned must dismiss their petition.

**CONCLUSION**

This petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance therewith.[2]

**IT IS SO ORDERED.**

_____ _____

DATE Laura D. Millman
Special Master

[2] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing his right to seek review.