In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 04-1041V
Filed: January 20, 2011
Unpublished

JENNIFER STONE, and GARY STONE, Parents and Next Friends of AMELIA STONE, a minor,	*	Decision on Remand; Factor unrelated to vaccine was "sole cause" and "principally responsible" for injury; Dravet syndrome, Severe myoclonic epilepsy of infancy (SMEI); Diphtheria, tetanus, acellular pertussis vaccine (DTaP)
Petitioners,	*	
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Decision on Remand[1]

Golkiewicz, Special Master.

Petitioners sought review of the undersigned's Decision denying their claim on behalf of their daughter, Amelia, for compensation pursuant to the National Vaccine Injury Compensation Program. Stone v. Sec'y of the Dept. of Health & Human Servs., No. 04-1041V, 2010 WL 1848220 (Fed. Cl. Spec. Mstr. Apr. 15, 2010) (hereinafter "Stone I"). On October 28, 2010, Senior Judge Margolis issued an opinion finding that the undersigned applied the incorrect legal standard in finding that respondent had successfully proven that Amelia's SCN1A gene mutation, and not her immunizations, was the cause of her condition, SMEI.[2] Citing 42 U.S.C.A. § 300aa-13(a)(2)(B) and the Federal Circuit's decision in De Bazan v. Sec'y of the Dept. of Health & Human Servs., 539 F.3d 1347 (Fed. Cir. 2008), Senior Judge Margolis determined that "[i]n order to enter judgment for respondent, the special master would have to

[1] The undersigned intends to post this decision on the website for the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). **As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision will be available to the public. Id. Any motion for redaction must be filed by no later than fourteen (14) days after filing date of this filing. Further, consistent with the statutory requirement, a motion for redaction must include a proposed redacted decision, order, ruling, etc.**

[2] SMEI stands for Severe Myoclonic Epilepsy of Infancy. It is also referred to as Dravet Syndrome in this case. This serious seizure disorder "[b]egins in the first year of life in previously healthy children. Hemiclonic seizures, which may be long lasting, are characteristic and can be associated with fever. Myoclonic, absence, tonic-clonic, and partial seizures also occur. The epilepsy is refractory and developmental regression ensues." Stone I, 2010 WL 1848220, at *1 (internal citations omitted).

have found that the SCN1A gene mutation was the 'sole cause' or 'principally responsible' for Amelia's SMEI." Stone v. Sec'y of the Dept. of Health & Human Servs., 95 Fed. Cl. 233, 238 (Fed. Cl. 2010)(hereinafter "Stone II"). The case was remanded for proceedings consistent with the Opinion. Id.

The undersigned conducted a status conference with the parties on October 28, 2010, to discuss Senior Judge Margolis' Opinion and to determine how to proceed. Minute Entry, October 29, 2010. In response to the undersigned's inquiries, the parties indicated no need or desire to introduce further expert testimony or evidence into the record, but agreed to submit further briefing. Order, filed October 29, 2010. Simultaneous briefs were due by November 29, 2010. Respondent filed her brief on November 29, 2010; petitioners filed their brief on November 30, 2010.

Respondent's brief discussed the parties' respective burdens and argued that because respondent "presented preponderant evidence that a factor unrelated was principally responsible for the alleged injury, petitioners cannot establish entitlement to compensation and their petition must be dismissed." R Memorandum, filed November 29, 2010. Petitioners' brief notes that the remand order only addressed one of petitioners' seven objections and argued that Amelia's "underlying propensity to seize[[3]] is not a defense to the injury of vaccine caused seizures." P Memorandum, filed November 30, 2010. Responsive briefs were due by December 13, 2010, Order, filed October 29, 2010; however, the parties did not file any responses.

The question to be answered on remand is quite narrow -- considering the record as a whole, does a preponderance of the evidence support a finding that the SCN1A gene mutation was the "sole cause" or was "principally responsible" for Amelia's SMEI? The undersigned answers emphatically, yes. The reasons are summarized below.[4]

For purposes of the following discussion, the undersigned adopts and affirms the entire discussion and findings from Stone I, except for the finding that respondent had proven that the SCN1A gene mutation was a "but for" and "substantial factor" cause of Amelia's SMEI. E.g., Stone I, 2010 WL 1848220, at *41-42. In lieu of this finding regarding respondent's proof and based upon the discussion and other findings in Stone I, the undersigned finds that respondent proved by a preponderance of the evidence that the SCN1A gene mutation was the sole cause and that it was principally responsible for Amelia's SMEI. It is emphasized that while the incorrect legal standard was used in Stone I to express my findings as to the weight accorded the parties' evidence, it was the undersigned's firm belief in resolving the case in the first instance, as it is my explicit finding now, that based upon the evidence in the record, Amelia's gene mutation was the sole cause of her SMEI.

[3] The undersigned notes that petitioners' characterization of Amelia's genetic condition as "an underlying propensity to seize" is arguably inconsistent with the medical evidence presented on her genetic mutation and her condition. However, given the resolution of the issues on remand, it is unnecessary to discuss this issue further.

[4] The following discussion presumes knowledge of Stone I. For ease of reference, pertinent citations will be to the Stone I decision, with citations to the record of Stone omitted.

Respondent's expert, Dr. Raymond was "relied upon heavily in deciding this case." Stone I, 2010 WL 1848220, at *13. Dr. Raymond is a board certified geneticist and neurologist with a specialty in child neurology. Stone I, 2010 WL 1848220, at *3 (internal citations omitted). His testimony was found to be "well explained, cogent, based upon the knowledge and practices of a clinical geneticist, and supported by the medical literature." Stone I, 2010 WL 1848220, *49. In contrast, petitioners' expert, Marcel Kinsbourne, was found unreliable and unpersuasive. Stone I, 2010 WL 1848220, at *12, 49-51. Dr. Raymond opined in his written report, R Ex J at 5, and testified that Amelia's SCN1A gene mutation was the **sole** cause of her SMEI. Transcript for May 15, 2009, Hearing at 331, 335, 357, 361-62; e.g., Stone I, 2010 WL 1848220, at *1, 13, 19, 40. Dr. Raymond's conclusion was based upon a comprehensive explication of the genetic information presented in this case, the medical literature concerning the relationship of the SCN1A gene mutation to SMEI, and Amelia's clinical findings. Based upon his consideration of the totality of information, Dr. Raymond testified, "if he was providing counseling to this family as a geneticist in his clinical practice, 'I would say to them this [, Amelia's SCN1A mutation,] is the sole cause of her Dravet syndrome[, SMEI]. . . ." Stone I, 2010 WL 1848220, at *19, 40.

As summarized in the Stone I Decision, the factors Dr. Raymond relied upon were:

- Amelia's mutation arose *de novo*;

- the mutation at issue results in a non-conservative amino acid change with the new amino acid having very different physical properties from what is found at the location in non-affected individuals;

- the mutation affects the pore of a sodium channel, a functionally important region;

- the mutation occurs in an area that is well-conserved across species, signaling significant ramifications when altered;

- there are reports evidencing similar or comparable mutations resulting in SMEI; and

- there is an absence of the mutation in the normal population.

Stone I, 2010 WL 1848220, at *19, 41. Dr. Raymond emphasized in his testimony, and the undersigned so found, that it was the presence of these cumulative factors and the clinical presentation in this case that convinced him that Amelia's SMEI was caused by the SCN1A gene mutation. See Stone I, 2010 WL 1848220, at *19, 25, 41. Dr. Raymond's testimony regarding the genetic issues went essentially unrebutted. See Stone I, 2010 WL 1848220, at *20 ("[P]etitioners [did not] offer the testimony of a geneticist to rebut the testimony of Dr. Raymond.")

Dr. Kinsbourne, petitioner's expert, recognized that SMEI has a "powerful" genetic component. Stone I, 2010 WL 1848220, at *19. However, Dr. Kinsbourne argued that "the pertussis vaccination caused fever, the fever triggered the seizure, the seizure lasted a long time" and caused damage by lowering Amelia's seizure "threshold." Id. Thus, as noted in the Stone I,

Dr. Kinsbourne agreed with the undersigned that the issue presented in the case "is the role of [Amelia's] initial seizure, this complex seizure[,] in altering whatever mutation we have." Id. Dr. Raymond and respondent's other expert in this case, Dr. Kohrman, conceded that the vaccine caused a fever in this case, which in turn may have triggered Amelia's initial complex febrile seizure. Stone I, 2010 WL 1848220, at *36. However, neither doctor saw any evidence that the vaccination or the initial seizure "caused any brain damage or injury that contributed to her SMEI." Id. As Dr. Raymond explained, "while complex febrile seizures **can** injure the brain, 'you have to put that in context of these cases **where we have no evidence that the complex febrile seizures actually injure the brain**; that their course was in any, shape or form different than any other individual who [has] Dravet syndrome.'" Id. (emphasis added in Stone I). There was simply no evidence of any role by the vaccination in the development of her SMEI and Dr. Kinsbourne offered no persuasive testimony to counter this testimony. Id.

Dr. Kinsbourne simply "inferred" damage from the initial seizure. Stone I, 2010 WL 1848220, at *36. This inference was in spite of Dr. Kinsbourne's agreement that "a trigger doesn't necessarily have to have a further deeper impact." Id. Dr. Kinsbourne also responded "no" to the undersigned's question of whether "there was any other clinical manifestation of the brain damage you maintain occurred." Id. Dr. Raymond testified that the typical age of onset of SMEI is two months to nine months and onset [of the first seizure] is associated with a temperature elevation. Id. Dr. Raymond stated that the temperature elevation does not "play any sort of causal role in the disease." Id. at 37. As Dr. Raymond explained, "[Amelia] had a fever from [the DPT] but her subsequent development of [SMEI] is completely unrelated to the fact she had an immunization that day." Stone I, 2010 WL 1848220, at *38.

Based upon Dr. Raymond's expertise and vastly superior testimony, Dr. Kinsbourne's unfortunately very weak testimony, the presence of genetic factors that when considered cumulatively by a geneticist enable the geneticist to opine to a genetic cause, id. at *19, *25, *41, and the absence of evidence that the complex febrile seizure actually injured the brain, id. at *36-*38, the undersigned is convinced beyond any doubt that respondent proved by a preponderance of the evidence that Amelia's SCN1A gene mutation was the sole cause and was principally responsible for her SMEI.

Petitioners are denied compensation. The Clerk of the Court is directed to enter judgment accordingly.[5]

[5] The undersigned notes that the issue of shifting burdens under the Act continues to be a matter of considerable debate. Respondent argued throughout that her burden to prove a factor unrelated never arose, that the burden never shifted to respondent; rather, respondent argued that the SCN1A evidence was offered in rebuttal to petitioner's *prima facie* case. See, e.g., Stone I, 2010 WL 1848220, at *11, n. 17.

My colleague explored the seemingly discordant precedent in Heinzelman v. Sec'y of the Dept. of Health & Human Servs., No 07-01V, 2008 WL 5479123, *4-16 (Fed. Cl. Spc. Mstr. Dec. 11, 2008)(resting ultimately upon the Federal Circuit assigning "the burden of ruling out other potential causes to the respondent"), *Motion for Review*, No. 07-01 (Fed. Cl. Jan. 6, 2011). Complicating the discussion further is the Federal Circuit's opinion in Doe/11 v. Sec'y of the Dept. of Health & Human Servs., 301 F.3d 1349, 1358 (Fed. Cir. 2010), where it appears the Circuit found that neither the statute nor prior Circuit precedent precludes the government from presenting evidence of alternative causation to rebut petitioner's case-in-chief. See also Walther v. Sec'y of the Dept. of Health & Human Servs., 485 F.3d 1146, 1151, n. 4 ("Where multiple causes act in concert to cause the injury, proof that the particular vaccine was a substantial cause may require the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine."); Shyface v. Sec'y of the Dept. of Health & Human Servs., 165 F.3d 1344, 1352 (adopting the Restatement (Second) of Torts rule for determining vaccine causation and acknowledging that contributing factors must be weighed when concurrent forces are alleged to bring about a single harm. "'Some other event which

IT IS SO ORDERED.[6]

s/ Gary J. Golkiewicz
Gary J. Golkiewicz
Special Master

---

is a contributing factor in producing the harm may have such a predominant effect in bringing it about as to make the effect of the actor's negligence insignificant and, therefore, to prevent it from being a substantial factor. So too, although no one of the contributing factors may have such a predominant effect, their combined effect may . . . so dilute the effect of the actor's negligence as to prevent it from being a substantial factor.'" Restatement (Second) of Torts § 433 cmt. d).

It is noted that in this case petitioner's expert agreed that Amelia's SMEI has a genetic basis, indeed "a very powerful one." Stone I, 2010 WL 1848220, at *19. The experts agreed that the vaccine caused a fever which may have triggered the initial seizure. Dr. Kinsbourne agreed with the undersigned that the issue in this case was the role of "this complex seizure in altering whatever mutation we have." Id. There appears to be Federal Circuit precedent supporting analysis of the SCN1A evidence in this case as a factor unrelated, rebuttal evidence, or as part of petitioner's case-in-chief under the Althen prongs. However, while this issue of burden shifting is not entirely clear, what is clear is that based upon the record as a whole, the SCN1A gene mutation is the cause of Amelia's SMEI. Therefore, it is unnecessary to resolve the burden-shifting issue since the preponderant, indeed the overwhelming, weight of the evidence is that the gene mutation is the **sole and principal** cause of Amelia's condition.

[6] This document constitutes a final "decision" in this case. Vaccine Rule 28.1. Unless a motion for review of this decision is filed within 30 days, the Clerk of the Court shall enter judgment in accord with this decision. Id.