

that “begins in the first year of life in previously healthy children” and results in “long lasting [seizures] . . . associated with fever.” (Dec. at 2 n.2.)

At the initial hearing, petitioners’ expert witness, Dr. Marcel Kinsbourne, testified that Amelia’s SMEI was caused by a DTaP¹ vaccination she received about four months after her birth. Respondent’s expert, Dr. Michael Kohrman, testified that Amelia’s SMEI was not caused by the vaccination, but rather by some “genetic predisposition;” Dr. Kohrman “hypothesized that Amelia’s Chromosome 20 duplication or other genetic predisposition caused her to suffer SMEI.” (*Id.* at 15.) After considering Dr. Kinsbourne and Dr. Kohrman’s testimony, the special master determined that “[n]othing in the record at the time of the first Hearing in this matter provided reliable evidence that Amelia’s seizure disorder was caused by factors unrelated to her vaccination.” (*Id.*)

Sometime after the hearing, Dr. Kohrman alerted the Court to “[n]ew and important data about genetics of vaccine associated encephalopathy and Dravet Syndrome,” published subsequent to his testimony. (*Id.* at 3.) The data suggested that SMEI is caused not by an adverse reaction to DTaP vaccine, but by a mutation in the Sodium Channel 1a subunit gene (“SCN1A”). (*See id.*) Amelia tested positive for the SCN1A gene mutation, and a second hearing was held to allow testimony on “SCN1A gene mutations in general,” and the “medical significance” of Amelia’s particular gene mutation. (*See id.* at 4.)

Respondent’s genetics expert, Dr. Gerald Raymond, testified that Amelia Stone’s SCN1A gene mutation is the sole cause of her SMEI. (*Id.* at 23-24.) Petitioners’ expert, Dr. Kinsbourne, testified that although SMEI has a “genetic component,” the DTaP vaccination “triggered the seizure,” and “caused damage by lowering Amelia’s seizure ‘threshold.’” (*Id.* at 26 (quoting Tr. R. 2 at 475).) After considering the parties’ evidence and arguments, the special master concluded that “respondent has demonstrated by a preponderance of the evidence that Amelia’s SCN1A gene mutation was more likely than not the ‘but for’ and ‘substantial factor’ that caused her [SMEI].” (*Id.* at 52.) Based on that finding, the special master entered judgment for respondent.

II. STANDARD OF REVIEW

The Vaccine Act provides that “the Court of Federal Claims may set aside the special master’s decision ‘only if the special master’s fact findings are arbitrary and capricious, its legal conclusions are not in accordance with law, or its discretionary rulings are an abuse of discretion.’” *Hazlehurst v. Sec’y of Health & Human Servs.*, 604 F.3d 1343, 1348-49 (Fed. Cir. 2010) (quoting *Turner v. Sec’y of Health & Human Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001)) (citing 42 U.S.C. § 300aa-12(e)(2)(B)). The Court’s review of the special master’s factual findings is “uniquely deferential;” the Court “may not second-guess the special master’s fact-intensive conclusions, particularly where the medical evidence of causation is in dispute.” *Id.* “In contrast, under the ‘not in accordance with law’ standard, the court reviews the special master’s legal conclusions de novo.” *Rodriguez v. Sec’y of Health & Human Servs.*, 91 Fed. Cl.

¹ “DTaP” stands for “Diphtheria-Tetanus-acellular-Pertussis.” (Dec. at 2.)

453, 461 (Fed. Cl. 2010) (citing *Saunders v. Sec'y of Health & Human Servs.*, 25 F.3d 1031, 1033 (Fed. Cir. 1994)).

III. ANALYSIS

Petitioners argue that the special master erred in finding “respondent’s burden in proving a ‘factor-unrelated’ defense to be **identical** to petitioner’s burden in proving their prima facie case.” (Pet. Mot. at 14 (citing Dec. at 10) (emphasis in original).) According to petitioners, “the Vaccine Act specifies a higher burden of proof for the respondent when she attempts to establish a factor unrelated defense.” (*Id.* at 15 (emphasis in original).) Respondent argues that the special master was correct in equating the parties’ respective burdens because “a factor unrelated must be both the ‘but for’ cause and also a ‘substantial factor’ in bringing about the injury.”² (Resp. Br. at 8-9.)

In order to prevail on a non-table³ Vaccine Act claim, the petitioner must make a prima facie showing that the vaccine was “not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (quoting *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)). It is well-settled that “the Vaccine Act does not require the petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case.” *Walther v. Sec’y of Health & Human Servs.*, 485 F.3d 1146, 1150 (Fed. Cir. 2007).

“If petitioners succeed in establishing a prima facie case of causation, the burden then shifts to the government to prove alternative causation by a preponderance of the evidence.” *Cedillo*, 617 F.3d at 1338. The Vaccine Act refers to this “alternative causation” as “factors unrelated to the administration of the vaccine.” 42 U.S.C. § 300aa-13(a)(2)(B). The Act specifies that:

. . . the term “factors unrelated to the administration of the vaccine”—

may, as documented by the petitioner’s evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents *principally responsible for causing* the petitioner’s illness, disability, injury, condition, or death.

² Respondent cites *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994), for the broad proposition that respondent’s burden is “identical to petitioners’ burden of proof.” (Resp. Br. at 9.) But as respondent explains elsewhere in its brief, *Knudsen* “equate[s] each parties’ burdens [only] in the sense that both parties must prove their cases by a preponderance of the evidence.” (*See id.* at 8.)

³ “The Vaccine Act distinguishes between so-called ‘Table injuries,’ for which causation is presumed when a designated condition follows the administration of a designated vaccine within a designated period of time, and all other injuries alleged to be caused by a vaccine, known as ‘off-Table injuries,’ for which causation must be proved in each case.” *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010) (citing 42 U.S.C. §§ 300aa-11(c), 300aa-14). In the instant case, petitioners have proceeded under an off-table theory.

Id. (emphasis added).

In *De Bazan v. Secretary of Health and Human Services*, 539 F.3d 1347, 1351-54 (Fed. Cir. 2008), the Federal Circuit explained that the standard for proving a “factor unrelated” is higher than the petitioner’s burden of proving a prima facie case. Although a petitioner is required to show that the vaccine was a “substantial factor” in causing his or her injury, “the petitioner need not show that the vaccine was the sole or predominant cause of her injury.” *Id.* at 1351. The respondent’s burden, by contrast, is to “identify[] a particular [unrelated] factor (or factors) and present[] sufficient evidence to establish that it was the *sole substantial factor* in bringing about the injury.”⁴ *Id.* at 1354 (emphasis added). In order to prevail, therefore, the respondent must “exclude[] the vaccine as a substantial factor.”⁵ *Id.*

In our case, the special master found that the petitioners met their burden of proving a prima facie case under the Vaccine Act. Indeed, the special master specifically noted that “petitioners would have likely demonstrated entitlement to compensation if respondent had not demonstrated that Amelia’s SMEI was caused by the genetic mutation located in her SCN1A gene.” (Dec. at 11.) In so holding, the special master pointed to *Simon* and *Mersburgh*, two cases in which he granted Vaccine Act claims based on evidence substantively identical to that which petitioners presented at the initial hearing. (*Id.* at 15 (citing Tr. R. 2 at 443; *Simon v. Sec’y of Health & Human Servs.*, No. 05-941V, 2007 WL 1772062, at *3 (Fed. Cl. Spec. Mstr. June 1, 2007); *Mersburgh v. Sec’y of Health & Human Servs.*, No. 04-997V, 2007 WL 5160384, at *3 (Fed. Cl. Spec. Mstr. July 9, 2007)).)

After finding that petitioners had made a prima facie case for compensation, the special master shifted the burden to respondent to prove the existence of a factor unrelated to the vaccine. (*See id.* at 16.) Consistent with § 300aa-13(a)(2)(B), the special master acknowledged that he must “analyze respondent’s evidence concerning Amelia’s SCN1A gene mutation *as a factor unrelated to her vaccination pursuant to §13(a)(1)(B).*” (*Id.* (emphasis added).) As such, the special master acknowledged that he would have to “utiliz[e] the highest standard under the Act.” (*Id.*)

But instead of finding that the SCN1A gene mutation was the “sole” or “principal” cause of Amelia’s SMEI, the special master held that “respondent has demonstrated by a preponderance of the evidence that Amelia’s SCN1A gene mutation was more likely than not the

⁴ See also *Whitener v. Sec’y of Health & Human Servs.*, No. 06-0477V, 2009 WL 3007380, at *26 (Fed. Cl. Sept. 2, 2009) (“[T]he [p]etition[er] is entitled to compensation, unless [r]espondent can proffer preponderant proof that a ‘factor unrelated’ was the sole or superseding cause of the injury.”); *Hargrove v. Sec’y of Health & Human Servs.*, No. 05-0694V, 2009 WL 1220986, at *40 (Fed. Cl. Apr. 14, 2009) (same); *Heinzelman v. Sec’y of Health & Human Servs.*, No. 07-01V, 2008 WL 5479123, at *16 (Fed. Cl. Dec. 11, 2008) (same).

⁵ The difference between “substantial factor” and “sole substantial factor” is a meaningful one. Indeed, this Court has consistently awarded compensation in cases where a factor unrelated was a substantial cause, but not the sole substantial cause, of a petitioner’s injuries. See, e.g., *Hargrove*, No. 05-0694V, 2009 WL 1220986, at *37 (granting petition for compensation where vaccine and proposed factor unrelated were “both . . . substantial causative factors”); *Garcia v. Sec’y of Health & Human Servs.*, No. 05-0720V, 2008 WL 5068934, at *12 (Fed. Cl. Nov. 12, 2008) (same); *Sword v. U.S.*, 44 Fed. Cl. 183, 188 (Fed. Cl. 1999) (same).

‘but for’ and ‘substantial factor’ that caused her [SMEI]” (*Id.* at 52 (emphasis added).) Nowhere in the opinion does the special master find that Amelia’s genetic mutation was “principally responsible” for or the “sole cause” of her injuries. The special master therefore failed to apply the correct legal standard to respondent’s evidence of a factor unrelated to the vaccine. *See* 42 U.S.C.A. § 300aa-13(a)(2)(B); *De Bazan*, 539 F.3d at 1354. In order to enter judgment for respondent, the special master would have to have found that the SCN1A gene mutation was the “sole cause” or “principally responsible” for Amelia’s SMEI. *See* 42 U.S.C.A. § 300aa-13(a)(2)(B); *De Bazan*, 539 F.3d at 1354.

Respondent concedes that the special master did not expressly find that the vaccine was the sole cause or principally responsible for Amelia’s SMEI. (*See* Trans. of Oral Argument at 34.) Nonetheless, respondent argues that it was “harmless error,” because “[Dr. Raymond] testi[fied] that the genetic mutation was the sole cause of the seizure disorder in this case.” (*Id.*) But testimony from respondent’s expert is no substitute for a finding of fact by the special master. *See* 42 U.S.C. § 300aa-12(d)(3)(A)(i) (“The decision of the special master shall . . . include findings of fact and conclusions of law”). Indeed, without an express determination from the special master that Amelia’s SCN1A mutation was the sole cause of her SMEI, the Vaccine Act precludes entry of judgment for respondent. *See De Bazan*, 539 F.3d at 1354; *see also, e.g., Hargrove*, No. 05-0694V, 2009 WL 1220986, at *40.

In the alternative, respondent argues that § 300aa-13(a)(2)(B), and therefore also the “principally responsible” standard, is inapplicable here because “Amelia’s genetic mutation is not an infection, toxin, trauma, or metabolic disturbance.” (Resp. Br. at 10.) It is well settled, however, that the list of potential unrelated factors in the Vaccine Act “is not meant to be all-inclusive.” *Finley v. Sec’y of Health & Human Servs.*, 55 Fed. Cl. 355, 361 (Fed. Cl. 2003) (citing *Hanlon v. Sec’y of Health & Human Servs.*, 40 Fed. Cl. 625, 631 (Fed. Cl. 1998)). Indeed, “factors unrelated ‘may include certain conditions listed, but also may include some other condition which is not listed, so long as that other condition has ‘no known relation to the vaccine involved, but which in the particular case [is] shown to have been the agent . . . principally responsible for causing’ the vaccine’s injury.’” *Id.* Respondent does not contest that Amelia’s SCN1A mutation had “no known relation” to the DTaP vaccine. Amelia’s genetic mutation therefore qualifies as a factor unrelated to the vaccine within the meaning of the Vaccine Act. Accordingly, the Court finds that the judgment in favor of respondent must be reversed.

IV. CONCLUSION

Petitioners’ motion for review is granted; the case is remanded to the special master for proceedings consistent with this opinion.⁶

s/ Lawrence S. Margolis
LAWRENCE S. MARGOLIS
Senior Judge, U.S. Court of Federal Claims

⁶ Since the case is being remanded to the Special Master for application of the correct legal standard, the Court need not rule on petitioners’ objections 2-7.