

In the United States Court of Federal Claims

No. 15-1016V

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NOT FOR PUBLICATION

**MARYELLEN KOTTENSTETTE and
NICHOLAS KOTTENSTETTE as best
friends of their daughter, C.K.,**

Petitioners,

v.

**SECRETARY OF HEALTH AND
HUMAN SERVICES,**

Respondent.

Keywords: Vaccine Act;
Motion for Review; Off-table;
Actual Causation; Legal
Standard

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MEMORANDUM OPINION AND ORDER

***HERTLING*, Judge**

The Secretary of Health and Human Services (HHS) moves this court to review the decision of a special master under the Vaccine Act, 42 U.S.C. § 300aa-11 et seq. *See Kottenstette v. Sec’y of HHS* [hereinafter *Decision*], No. 15-1016V, 2017 WL 6601878 (Fed. Cl. Spec. Mstr. Dec. 12, 2017). The special master found that a pertussis vaccine administered to Maryellen and Nicholas Kottenstette’s then-four-month old daughter, C.K., substantially caused C.K.’s developmental disabilities. The Court grants the Secretary’s motion, vacates the special master’s decision, and remands the case for reconsideration under the correct legal standard in

* Pursuant to Vaccine Rule 18(b), this opinion was initially filed on February 12, 2020, and the parties were afforded 14 days after the filing of this opinion within which to notify the court of any information that should be redacted from this decision for reasons of privilege or confidentiality. The parties did not propose any redactions. Accordingly, this opinion is reissued in its original form for posting on the Court’s website.

light of the Federal Circuit’s intervening decision in *Boatmon v. Secretary of HHS*, 941 F.3d 1351 (Fed. Cir. 2019).

I. BACKGROUND

A. Facts Underlying the Petitioners’ Claim

C.K. received the DTaP formulation of the pertussis vaccine, along with other vaccines, at her four-month wellness visit in October 2012. That same day, and again four days later, C.K.’s parents observed her moving her arms, legs, and shoulders in a manner that a treating neurologist determined was consistent with infantile spasms, a seizure disorder. As of June 2017, C.K. had physical disabilities that “impact her functional mobility, postural stability, eye-hand coordination, fine motor control, pre-writing skills, and self-care skills.” *Decision* at *3. The special master found that the DTaP vaccine was a “substantial cause” of C.K.’s developmental disabilities because the vaccine hastened the onset of the brain-damaging infantile spasms that C.K. otherwise might only have experienced later in her development.

B. The Special Master’s Decision

The special master found that C.K.’s vaccinations caused C.K.’s “afebrile infantile spasms and a non-Table chronic encephalopathy” (brain damage).¹ *Decision* at *1.

The special master’s decision, first, summarized the facts of C.K.’s vaccination, symptoms, and treatment along with the expert reports, medical literature, and testimony submitted as evidence of causation. The decision then described the Vaccine Act’s preponderant evidence standard and introduced the standard *Althen* “prongs” used to analyze actual causation under that standard. *See Moberly v. Sec’y of HHS*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010) (citing *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)). Then, without reference to the specific *Althen* prongs, the special master articulated the following nine premises related to proof of vaccine causation:

1. Showing an absence of alternate causes or mere temporal association is insufficient to prove causation in fact. *Decision* at *12 (citing *Grant v. Sec’y of Dept. of HHS*, 956 F.2d 1144, 1149 (Fed. Cir. 1992)).
2. Petitioners must show that C.K.’s vaccinations were “substantial factors in causing,” not merely a but-for cause, of C.K.’s infantile spasms and “chronic neuropathy.” *Decision* at *12 (citing *Shyface v. Sec’y of HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)).
3. “[R]equiring either epidemiologic studies . . . or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect” is contrary to the Federal Circuit’s *Althen* decision, which approved the use of circumstantial evidence

¹ The special master also found that the petitioners had failed to prove a Table encephalopathy. *Decision* at *1.

to prove causation. *Decision* at *12 (citing *Capizzano v. Sec’y of HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006)).

4. The Vaccine Act’s preponderant evidence standard does not require “objective confirmation” of causation. *Decision* at *12 (citing *Althen*, 418 F.3d at 1279).
5. “[T]he purpose of the Vaccine Act’s preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” *Decision* at *12 (quoting *Althen*, 418 F.3d at 1280).
6. “[C]lose calls are to be resolved in favor of petitioners.” *Decision* at *12 (citing *Capizzano*, 440 F.3d at 1327; *Althen*, 418 F.3d at 1280). As an example, the special master explained that the *Althen* decision found a causal link between a vaccine and two conditions that the Federal Circuit recognized was “a sequence hitherto unproven in medicine.” *Decision* at *12 (quoting *Althen*, 418 F.3d at 1280).
7. An explanation of causation must have “biologic credibility” rather than proof of an exact causal mechanism. *Decision* at *12. The special master explained that she looked for a “medical explanation of cause and effect and *medical probability* rather than certainty.” *Decision* at *12 (citations omitted) (emphasis added). The special master offered her definition of “medical probability” as “biologic credibility rather than specification of an exact biologic mechanism.” To support this conclusion, the special master quoted language from the Federal Circuit’s decision in *Knudsen v. Secretary of the Department of HHS* providing that a requirement to identify and prove “specific biological mechanisms would be inconsistent with the Vaccine Act’s purpose and nature” as an easier and more generous alternative to “full-blown tort litigation” and not a “vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.” *Decision* at *12 (quoting *Knudsen v. Sec’y of the Dep’t of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994) (citing H. Rep. No. 99-908, at 3, reprinted in 1986 U.S.C.C.A.N. 6344, 6348)).
8. “Bare statistical” evidence is not probative of alternate causation. *Decision* at *13 (citing *Knudsen*, 35 F.3d at 550).
9. “[W]hen a vaccine fits within an epidemiological study, that alone is sufficient proof of vaccine causation[.]” *Decision* at *13. The special master quoted language from *Knudsen* to support this proposition:

Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules. The determination of causation in fact under the Vaccine Act involves ascertaining whether a sequence of cause and effect is “logical” and legally probable, not medically or scientifically certain. [citing cases] Thus, for example, causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular child without detailed

medical and scientific exposition on the biological mechanisms.
[citing case].

Decision at *13 (quoting *Knudsen*, 35 F.3d at 548-49) (alterations in original).

Relying on *Knudsen* and another special master's decision, the special master asserted that "when a [vaccine recipient] would fit within an epidemiological study, that alone is sufficient proof of vaccine causation." *Decision* at *13, 14; see *Knudsen*, 35 F.3d at 548-49; *H.J. v. Sec'y of HHS*, No. 11-301V, 2015 WL 6848357 (Fed. Cl. Spec. Mstr. Nov. 6, 2015). The special master then concluded, "because CK would have qualified to have been in the Bellman and Melchior studies, the undersigned finds that her four-month vaccinations triggered the onset of her cryptogenic seizures."

The special master concluded her decision with a short paragraph titled "*Althen* Analysis" that dedicated one sentence to each prong:

Under *Althen* Prong One, the undersigned finds that DTaP vaccine can trigger the onset of infantile spasms. Under *Althen* Prong Two, the undersigned finds that there was a logical sequence of cause and effect in DTaP causing CK's onset of infantile spasms. Under *Althen* Prong Three, the undersigned finds that an onset within hours of DTaP vaccination is consistent with the effect of the vaccine's triggering an abrupt onset.

Decision at *15.

II. STANDARD OF REVIEW

Under the Vaccine Act, this Court reviews a special master's decision only to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Althen*, 418 F.3d at 1277 (quoting 42 U.S.C. § 300aa-12(e)(2)(B)). More specifically, the Court considers a special master's interpretation of statutes and other legal rules anew, without deference to the special master. *Hines on Behalf of Sevier v. Sec'y of Dep't of HHS*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). The Court defers, however, to the special master's factual findings as long as the special master has (1) "considered the relevant evidence of record," (2) "drawn plausible inferences," and (3) "articulated a rational basis for the decision." *Id.*

Under the arbitrary and capricious standard, the Court does not "reweigh" or re-evaluate the evidence. *Porter v. Sec'y of HHS*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). The Court does not re-examine the probative value of the evidence or a witness's credibility. *Id.*

III. ANALYSIS

The "biologic credibility" standard the special master applied to proof of the petitioners' causal theory under *Althen*'s first prong is not sufficiently distinguishable from the "plausible" or "reasonable" standard that the Federal Circuit rejected in *Boatmon*. Without reweighing particular evidence, the Court finds apparent from the special master's description of the

evidence that the petitioners' causal theory was only *plausibly* linked to the DTaP vaccine at issue, and only *plausibly* linked to the developmental injury C.K. suffered. This approach, along with the special master's alternative approach to proof of causation that fit the petitioners' case into an existing study—the study itself only plausibly applicable to the vaccine at issue—indicates that the wrong standard for proof of causation, clarified by the Federal Circuit after the special master's decision under review, was applied in this case.

The Vaccine Act requires preponderant evidence of causation. 42 U.S.C. § 300aa-13(a)(1)(A). A petitioner must show the harm was more likely than not caused by the vaccine. *Althen's* three prongs, together, enumerate the facts that are relevant and essential to prove causation in cases such as this one, in which the possibility of injury is not already recognized in the Vaccine Table. *Althen* requires “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” 418 F.3d at 1278.

The first *Althen* prong steps back from the question of whether the vaccine caused a petitioner's injury in the particular case and requires a causal theory that explains how the kind of vaccine the petitioner received could cause the same kind of injury the petitioner alleged. After proving the first *Althen* prong, a petitioner must still prove a logical sequence of events (the second prong) and a degree of temporal proximity between vaccination and injury (the third prong) that fit the first prong's causal theory. The first-prong causal theory, then, influences which facts are relevant in proving the second and third prongs. Without a general first-prong causal theory to show the fact-finder what vaccine causation is most likely to look like, the fact-finder has no criteria to measure the specific facts of a petitioner's case.

Language in earlier decisions suggested that *Althen's* first prong could be satisfied by showing it was “reasonable” or “plausible” that a vaccine can cause the same kind of injury a petitioner alleged. The Federal Circuit has now explicitly rejected that proposition in *Boatmon*. 941 F.3d at 1359-60. More specifically, the first prong's medical or scientific causal theory must be “reputable.” *Id.* at 1359 (quoting *Moberly*, 592 F.3d at 1322). “While it does not require medical or scientific certainty, it must still be ‘sound and reliable.’” *Id.* (quoting *Knudsen*, 35 F.3d at 548).

The standard of proof required for a first-prong causal theory is the fulcrum of *Althen's* usefulness. If a petitioner could satisfy *Althen's* first prong with any causal theory that is merely *plausible*—understood here to mean “reasonably possible”—proving the second and third *Althen* prongs would only show that the petitioner's injury was plausibly caused by receipt of the vaccine. Evidence that the petitioner's facts under prongs two and three are consistent with a general causal theory does not make the general causal theory itself more likely to be true.

The special master's explicit discussion of *Althen's* first prong spanned only one sentence. *Decision* at *15. This sentence and other relevant parts of the special master's discussion, taken together, reveal that the special master adopted the causal theory that unexplained infantile spasms are not caused by vaccines, but that the DTaP vaccine “can trigger the onset of infantile spasms,” *id.*, and this earlier onset of the seizure disorder causes more

severe damage to the brain's psychomotor development than the seizures would have caused at their natural, later time of onset. *Decision* at *14. The special master cited the conclusions of the Bellman and Melchior studies and the opinion of the petitioners' expert, Dr. Marcel Kinsbourne, as support for this theory.²

The special master's stated reasons for adopting critical elements of the petitioners' causal theory could only have been sufficient under a lower legal standard than the "reputable, sound and reliable" standard required by *Boatmon*. First, the special master relied on an expert's unsupported assertion that studies of infantile spasms caused by another vaccine applied to the vaccine at issue in this case. Second, the special master relied on an expert's opinion that the overall causal theory, including the ultimate link to developmental disabilities, was—in the special master's own words—"plausible." The special master's reliance on the fit between the facts of C.K.'s case and the cited epidemiological studies, however, is not an adequate substitute for the analysis required under *Althen*'s three prongs.

A. Causal Link to the DTaP Vaccine

The special master relied on two studies as evidence connecting the pertussis vaccine with infantile spasms. The Bellman and Melchior studies analyzed infants' reactions to the DTP formulation of the pertussis vaccine. The study suggested that DTP could trigger, but not cause, unexplained infantile spasms in infants who were predisposed to have them. *Decision* at *13, 14.

The special master, however, offered no basis for connecting the DPT formulation of the pertussis vaccine tested in the cited studies to the DTaP formulation of the pertussis vaccine at issue in this case. The special master asked Dr. Kinsbourne "if he agreed that the results of the Bellman . . . study . . . [were] applicable to children who receive [DTaP], just at a lower incidence." *Decision* at *9. The special master reported that Dr. Kinsbourne "absolutely agreed." *Id.*

The special master did not explain the basis of Dr. Kinsbourne's opinion and did not offer an independent basis for applying the DPT-study findings to the DTaP vaccine. Without any explanation for the special master's acceptance of this conclusion, the Court finds the special master's inference that the DPT study applies to the DTaP formulation at lower rates to be arbitrary and capricious. *See Boatmon*, 941 F.3d 1360-61 ("Here there is nothing more than the assertion of [the expert witness].").

B. Causal Link to Developmental Injuries

The special master summarized Dr. Kinsbourne's testimony on the connection between the DTaP vaccine and developmental injuries. This summary implicitly addressed all three

² *See* M.H. Bellman et al., Infantile Spasms and Pertussis Immunisation, 321 *Lancet* 1031-34 (1983); J.C. Melchior, Infantile Spasms and Early Immunization Against Whooping Cough: Danish Survey from 1970 to 1975, 52 *Archives of Disease in Childhood* 134-37 (1977).

Althen prongs, describing a causal link between C.K.’s disabilities and the infantile spasms, discussing the temporal proximity, and explicitly finding the causal link “plausible”:

. . . CK has severe and mainly refractory seizures that degraded her mental development so that she is now profoundly mentally retarded.

Dr. Kinsbourne concludes that, but for her vaccinations, CK’s cryptogenic infantile spasms would not have led to such a devastating result. He also writes that the one-day interval between vaccinations and first infantile spasms is medically reasonable since her innate immune system rapidly responded to the vaccinations. He also states that it is *plausible* that routine vaccinations can trigger infantile spasms in a susceptible child, resulting in severe psychomotor regression.

Decision at *5-6 (citations omitted) (emphasis added).

The special master’s characterization of Dr. Kinsbourne’s conclusion is indistinguishable from the reasoning rejected as contrary to law in *Boatmon*. See *Boatmon*, 941 F.3d at 1359-60.

C. Proof by Epidemiological Evidence

In general, the special master’s nine premises, including the premise that articulation of an exact biological mechanism is not necessary to prove vaccine causation, are well-taken. The special master’s articulation of these premises, however, suggests they were offered as alternative support for the petitioners’ causal theory, which, as discussed above, was plausible or reasonable, but insufficient to satisfy *Althen*’s first prong. The special master appears to have relied on these nine premises to put a thumb on the scale, without explicitly analyzing under *Althen*’s first prong the applicability of the petitioners’ causal theory to the vaccine and the kind of injury at issue.

Specifically, the special master noted that the close match between the immediate onset of C.K.’s infantile spasms and the similarly immediate onset of infantile spasms among subjects in the Bellman study were dispositive as to the issue of causation in this case. The special master interpreted the Federal Circuit’s opinion in *Knudsen* to signify that causation could be found “based on epidemiological evidence and the clinical picture regarding the particular child without detailed medical and scientific exposition on the biological mechanisms.” *Decision* at *14. The special master provided that this principle “governs the outcome of this decision.” *Id.* As support, the special master cited similar reasoning in *H.J. v. Sec’y of HHS*, No. 11-301V, 2015 WL 6848357, at *9 (Fed. Cl. Nov. 6, 2015).

Knudsen held that the government may defeat a petitioner’s claim of vaccine causation with a theory of viral infection even if the virus is not identified “in the particular case” by a specific type or name. *Knudsen*, 35 F.3d at 549. The government still must prove, however, “that there was in fact a viral infection, and that the viral infection ‘in the particular case [was]

. . . principally responsible for *causing* the petitioner’s illness, disability, injury, condition, or death.” *Id.* (quoting 42 U.S.C. § 300aa–13(a)(2) (emphasis in original)).

Open-ended statements in *Knudsen*’s reasoning rejecting the need for “scientific certainty” or “specific biological mechanisms” in proof of vaccine causation should not be applied beyond that case’s narrow holding and should not be taken to loosen the requirements of *Althen*, which was decided almost 11 years later. *Althen* cites the relevant part of *Knudsen* as indirect support (“*see*”) for *Althen*’s conclusion that requiring that literature objectively confirm the medical plausibility of a petitioner’s claim would be inconsistent with the Vaccine Act’s legislative purpose. *Althen*, 418 F.3d at 1279 (citing *Knudsen*, 35 F.3d at 549).

As an example of causation based on fitting the petitioner’s case to an epidemiological study, *Knudsen* cites *Jay v. Secretary of the Department of HHS*. 998 F.2d 979, 984 (Fed. Cir. 1993). In *Jay*, however, the Federal Circuit found a *table* injury, and then it found that the vaccine caused death as a sequela of the table injury. *Id.* For table injuries, the mechanism may not be known or the theory may be more uncertain, but their formal recognition by rulemaking places them outside of the Vaccine Act’s standard of proof for actual causation for non-table injuries. *See Moberly*, 592 F.3d at 1322.

In summary, the court finds no support in Federal Circuit or this Court’s case law for proving actual causation by fitting a petitioner’s case into an epidemiological study without also providing a “reputable,” “sound and reliable” causal theory to satisfy *Althen*’s first prong.

IV. CONCLUSION

The special master erred by applying the wrong legal standard to the petitioners’ causal theory. The respondent’s motion for review is **GRANTED**, the special master’s decision is **VACATED**, and the case is **REMANDED** so that the special master may consider the petitioners’ theory and evidence under the correct legal standard.

It is so **ORDERED**.

s/ Richard A. Hertling

Richard A. Hertling
Judge