

In the United States Court of Federal Claims

No. 18-800V

(Filed Under Seal: June 29, 2021)*

(Reissued: July 29, 2021)

FOR PUBLICATION

SCOTT GERMAINE, Individually *
and on behalf of his minor grandson, *
C.G., *

Petitioner, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

OPINION AND ORDER

Petitioner Scott Germaine seeks relief under the National Childhood Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 to 34, on behalf of his grandson C.G., who experienced intussusception after receiving the third dose of a rotavirus vaccine.¹ The Special Master denied the petition based on a finding that Mr. Germaine “has not established a persuasive medical theory connecting the third dose of the [rotavirus] vaccine with intussusception[.]” Special Master’s Decision (“SMD”) at 1 (ECF 62). That conclusion was not arbitrary or capricious, and is therefore **SUSTAINED**.

To obtain compensation under the National Childhood Vaccine Injury Compensation Program, a petitioner must prove that a vaccine caused an injury. *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). There are two ways to show causation: (1) through “a statutorily-prescribed presumption of causation upon a showing that the injury falls under the Vaccine Injury Table (“Table injury”),” *id.* (citing 42 U.S.C. § 300aa-14(a)), or (2) by proof of causation in fact “where the complained-of injury is not listed in the Vaccine Injury Table (“off-Table injury”),”

* This Opinion was issued under seal on June 29, 2021. The parties were directed to propose redactions by July 13, 2021. No proposed redactions were submitted. The Court hereby releases publicly the Opinion and Order of June 29 in full.

¹ This Court has jurisdiction. *See* 42 U.S.C. §§ 300aa-11(c), 300aa-16(a). Mr. Germaine timely moved for review. *See* 42 U.S.C. § 300aa-12(e)(1).

id. (citing 42 U.S.C. §§ 300aa-13(a)(1), 300aa-11(c)(1)(C)(ii)(I)). For off-Table injuries, causation in fact has three elements: “(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.” *Id.*² The sole question presented by the motion for review — and the only issue discussed by the Special Master — is whether Mr. Germaine satisfied the first of those elements.

Intussusception between 1 and 21 days after a child’s first or second dose of a rotavirus vaccine is a “Table injury” where causation is presumed. 42 C.F.R. § 100.3(a)(XI) (vaccine table). But intussusception after the third dose is not. *See* 42 C.F.R. § 100.3(c)(4)(ii)(A) (“For purposes of paragraph (a) of this section, the following shall not be considered to be a Table intussusception: ... Onset that occurs with or after the third dose of a vaccine containing rotavirus[.]”); *see also* National Vaccine Injury Compensation Program: Addition of Intussusception as Injury for Rotavirus Vaccines to the Vaccine Injury Table, 80 Fed. Reg. 35848, 35849 (June 23, 2015) (“The definition for presumption of vaccine causation only applies to the first and second dose of vaccine, and excludes intussusception occurring with or after the third dose. The third dose of rotavirus vaccines lacks sufficient evidence showing risk.”). Plaintiff must therefore prove causation in fact by preponderance of the evidence. *See, e.g., Althen*, 418 F.3d at 1278.

One way to show causation in fact is by establishing a “probable” biological mechanism for how the third dose of the rotavirus caused C.G.’s intussusception. *Knudsen*, 35 F.3d at 548–49. Mr. Germaine argues that intussusception could be caused by an “inflammatory response” to the rotavirus vaccine, Pet.’s Mot. for Rev. at 5 (ECF 64), but the Special Master found that Mr. Germaine “has not carried his burden of proof based on the biological mechanism alone,” SMD at 8, a factual conclusion that should be upheld unless arbitrary or capricious. *Munn v. Sec’y of Dep’t of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992); 42 U.S.C. § 300aa-12(e)(2)(B).

The Special Master did not err. Beyond the generic reference to “inflammation,” little additional explanation appears in the Motion for Review or in the record before the Special Master. Without more detail, Mr. Germaine’s theory is not specific to the third dose of the rotavirus vaccine, and possibly not even to rotavirus vaccines as opposed to other vaccines. Nor is there any evidence that C.G. *personally* experienced inflammation that caused intussusception. *See Knudsen*, 35 F.3d at 549. Mr. Germaine’s proposed mechanism thus cannot be a “probable” one. *Id.* at 548–49. It is only a hypothesis, a theoretical possibility. Although proof of

² The government can rebut proof of causation by showing, “also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.” *Althen*, 418 F.3d at 1278 (quoting *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994)); *see* 42 U.S.C. § 300aa-13(a)(1)(B).

causation does not “require identification and proof of specific biological mechanisms,” *id.* at 549, “a ‘plausible’ or ‘possible’ causal theory” is not enough, *see Boatmon v. Sec’y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019); *see also Broekelschen v. Sec’y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (“[A] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner’s case[.]”).

Causation can also be shown by epidemiological evidence, *i.e.*, by connecting medical literature about vaccine complications to a patient’s clinical record. *Knudsen*, 35 F.3d at 549 (explaining that “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”). Mr. Germaine identified several studies purportedly showing a risk of intussusception after rotavirus vaccines. The Special Master discussed several of those studies, but concluded that none of them showed an association between the third dose of a rotavirus vaccine and intussusception. SMD at 11. That conclusion, likewise, must be upheld unless arbitrary or capricious. 42 U.S.C. § 300aa-12(e)(2)(B).

Mr. Germaine claims the Special Master misinterpreted two studies.³ *First*, he proposes a different reading of Haber, *et al.*, *Intussusception After Rotavirus Vaccines Reported to US VAERS, 2006-2012*, 131 *Pediatrics* 1042 (2013) (ECF 21). Mr. Germaine claims the Special Master overlooked Haber’s finding that “out of the 584 confirmed cases of intussusception after [the rotavirus vaccine with a three-dose protocol], 29% (169 reports) were reported after dose 3.” Pet.’s Mot. for Rev. at 5.

That argument makes little sense. If instances of intussusception were equally distributed across a three-dose vaccine, one would expect each dose to be associated with one-third of the intussusception cases. The fact that the third dose of the rotavirus vaccine is associated with slightly *less* than a third of the reported intussusception cases — especially without any statistical analysis — does not advance Mr. Germaine’s argument that Haber found “an increased risk of intussusception after the third dose[.]” *Id.*

³ Any objections to the Special Master’s analysis of other studies are forfeited. *See* RCFC App. B, Rule 24(b)(1) (requiring that motions for review of special master decisions must “fully and specifically state and support each objection” to the special master’s opinion); *Yalacki v. Sec’y of Health & Hum. Servs.*, 146 Fed. Cl. 80, 92 n.5 (2019). Although I need not reach the issue, the weight of the remaining evidence would likely support the Special Master’s conclusion concerning causation even if Mr. Germaine’s objections were meritorious. *See Hines v. Sec’y of Dep’t of Health & Hum. Servs.*, 940 F.2d 1518, 1526 (Fed. Cir. 1991) (“[E]ven if it was error, it was harmless because, as explained below, the special master’s decision was based on a number of factors and [petitioner] has not shown that reliance on the judicially noticed incubation period derived from the textbook was likely critical to the result.”); *Doe/11 ex rel. Child/Doe/11 v. Sec’y of Dep’t of Health & Hum. Servs.*, 87 Fed. Cl. 1, 12 (2009) (“Even removing consideration of the skewed study and the Special Master’s extrapolation of [an infant’s] length, substantial evidence supports the Special Master’s conclusion that Petitioners failed to prove a prima facie case[.]”), *aff’d sub nom. Doe v. Sec’y of Health & Hum. Servs.*, 601 F.3d 1349 (Fed. Cir. 2010).

More importantly, Mr. Germaine ignores Haber's *analysis* of the raw numbers. Haber calculated the "excess risk" of intussusception associated with rotavirus vaccinations. Haber at 1044. Excess risk is a method of describing how a given risk factor affects the likelihood of death or disease compared with the background rate. Excess risk is derived from the related concept of "relative risk," which is "[t]he ratio of the risk of disease or death among people exposed to an agent to the risk among the unexposed." Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 627 (3d Ed. 2011). "A relative risk of 1 indicates no association between association and disease." *Id.* Excess risk is equal to relative risk minus 1.0, such that a positive number means a positive association between the risk factor and a given outcome, and a negative number means a negative relationship. Haber found that while the first and second doses were associated with a modestly positive excess risk (0.74 and 0.21 per 100,000, respectively), the third dose was associated with a *negative* excess risk (-0.16 per 100,000), *i.e.*, a *reduction* in the risk of intussusception. Haber at 1046, 1047.

That excess risk figure, moreover, has to be taken with its statistical context. Haber found that the excess risk associated with the third dose of the rotavirus vaccine had a "confidence interval" of -0.38 to 0.27. *Id.* A "confidence interval" is "[a] range of values ... within which the true value is likely to fall[.]" *Reference Manual on Scientific Evidence* 621. A confidence interval that straddles a relative risk of 1.0 (that is, an excess risk of 0.0) is "statistically insignificant," *see id.*, meaning that it is statistically indistinguishable from *no* change in risk. Haber's data, properly understood, do not show that the third dose of a rotavirus vaccine has any statistically significant association with rates of intussusception. Haber therefore contradicts Mr. Germaine's argument that the study found "an increased risk of intussusception after the third dose[.]" Pet.'s Mot. for Rev. at 5.

Second, Mr. Germaine emphasizes that Koch, *et al.*, *Risk of Intussusception After Rotavirus Vaccination*, 114 *Deutsches Ärzteblatt Int'l* 255 (2017) (ECF 21), found the "relative risk" of intussusception after the third dose was 1.14, "which demonstrates an increased relative risk of intussusception after the third dose[.]" Pet.'s Mot. for Rev. at 6. Mr. Germaine is correct that a relative risk greater than 1.0 refers to an increased risk of an outcome, *see Reference Manual on Scientific Evidence* 627, but once more he overlooks the confidence interval: 0.75 to 1.74. Koch at 255, 259. The small increased relative risk, in other words, was statistically insignificant — indistinguishable from no increased risk at all. That is why Koch concluded — rightly, from a statistical perspective — that there is no increased risk of intussusception after the third dose of a rotavirus vaccine. *Id.* at 260. The Special Master, in turn, did not err in relying on that conclusion.

CONCLUSION

For the foregoing reasons, the motion for review is **DENIED** and the decision of the Special Master is **SUSTAINED**.

The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Stephen S. Schwartz
STEPHEN S. SCHWARTZ
Judge